

Exhibit C

Table of Intrinsic Evidence Exhibits

Exhibit No.	Document Description
1.	U.S. Patent No. 8,190,223
2.	File History Excerpts for U.S. Patent No. 8,190,223
3.	Patent No. EP 2 305 104
4.	U.S. Patent No. 7,027,849
5.	U.S. Patent No. 7,764,982
6.	U.S. Patent Application Publication No. 2002/0082488
7.	International Publication No. WO 2006/094168
8.	U.S. Patent No. 10,736,507
9.	File History Excerpts for U.S. Patent No. 10,736,507
10.	File History Excerpts for U.S. Patent No. 9,877,650
11.	U.S. Patent Application Publication No. 2008/0071153
12.	U.S. Patent Application Publication No. 2008/0211657
13.	U.S. Patent Application Publication No. 2010/0160798
14.	U.S. Patent Application Publication No. 2010/0198094
15.	U.S. Patent Application Publication No. 2011/0077473
16.	U.S. Patent Application Publication No. 2012/0226117
17.	U.S. Patent No. 10,984,911
18.	U.S. Provisional No. 60/657,596
19.	File History Excerpts for U.S. Patent No. 10,984,911
20.	U.S. Patent No. 6,580,086
21.	U.S. Patent No. 8,781,544

EXHIBIT 1



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(12) **United States Patent**
Al-Ali et al.

(10) **Patent No.:** **US 8,190,223 B2**
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(54) **NONINVASIVE MULTI-PARAMETER
PATIENT MONITOR**

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(73) Assignee: **Masimo Laboratories, Inc.**, Irvine, CA (US)

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(57) **ABSTRACT**

Embodiments of the present disclosure include a handheld multi-parameter patient monitor capable of determining multiple physiological parameters from the output of a light sensitive detector capable of detecting light attenuated by body tissue. For example, in an embodiment, the monitor is capable of advantageously and accurately displaying one or more of pulse rate, plethysmograph data, perfusion quality, signal confidence, and values of blood constituents in body tissue, including for example, arterial carbon monoxide saturation ("HbCO"), methemoglobin saturation ("HbMet"), total hemoglobin ("Hbt"), arterial oxygen saturation ("SpO₂"), fractional arterial oxygen saturation ("SpaO₂"), or the like. In an embodiment, the monitor advantageously includes a plurality of display modes enabling more parameter data to be displayed than the available physical display real estate.

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A61B 5/1455 (2006.01)

(52) **U.S. Cl.** **600/310**; 600/323; 600/324; 600/326

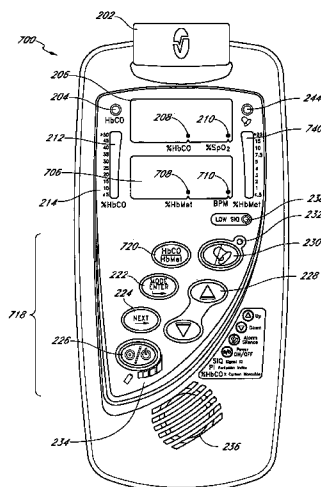
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See application file for complete search history.

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47 Claims, 18 Drawing Sheets



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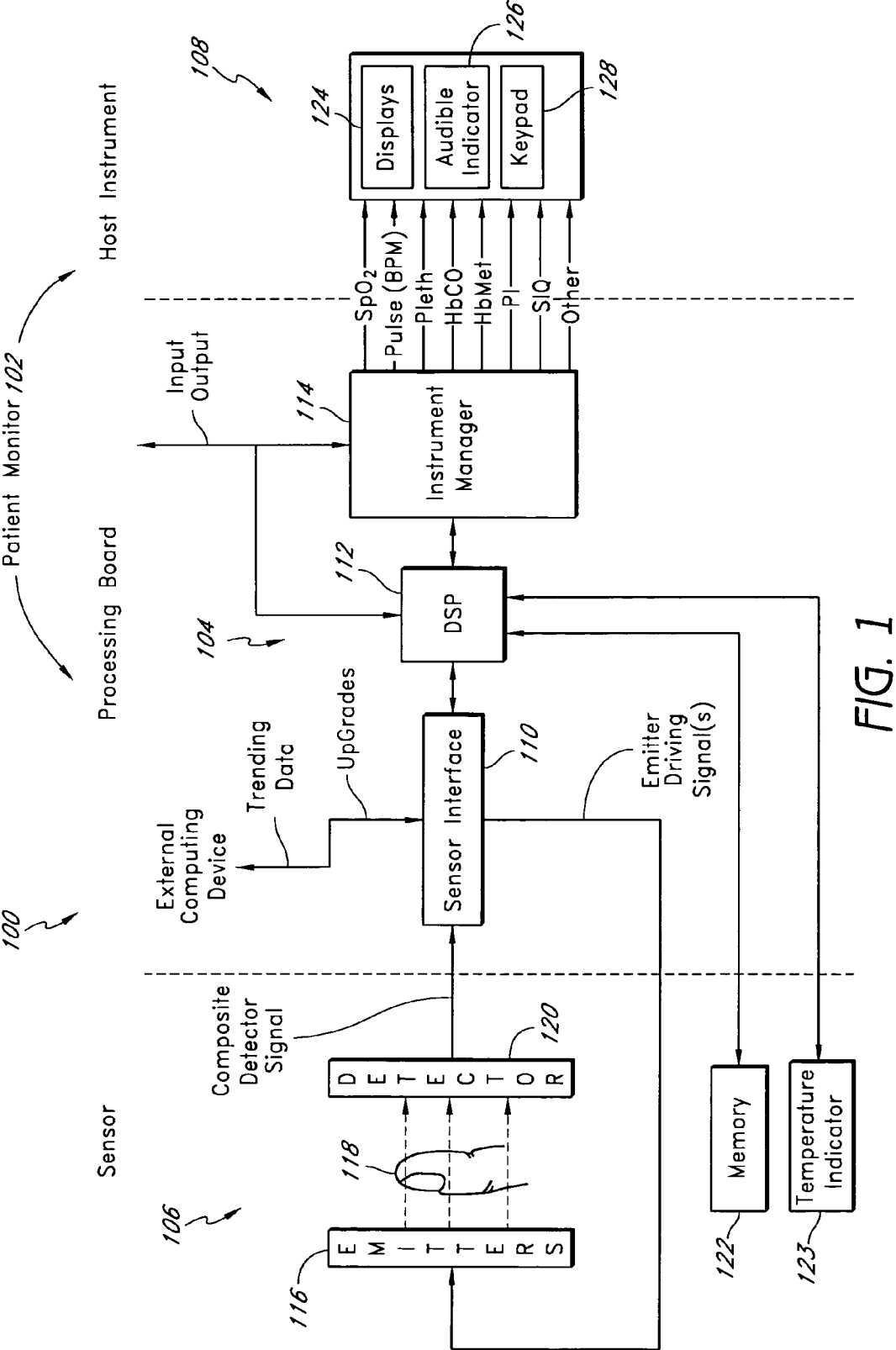


FIG. 1

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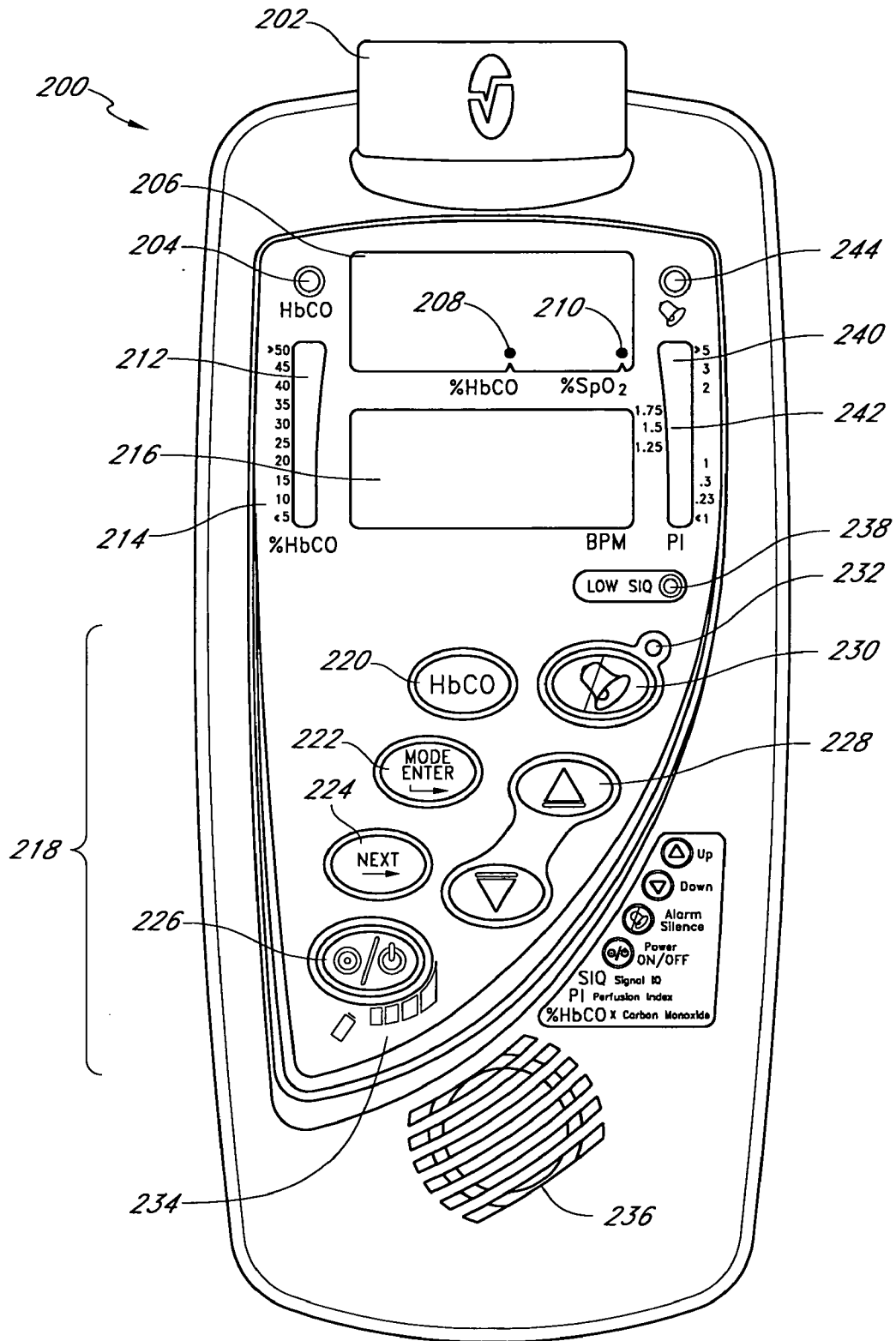


FIG. 2

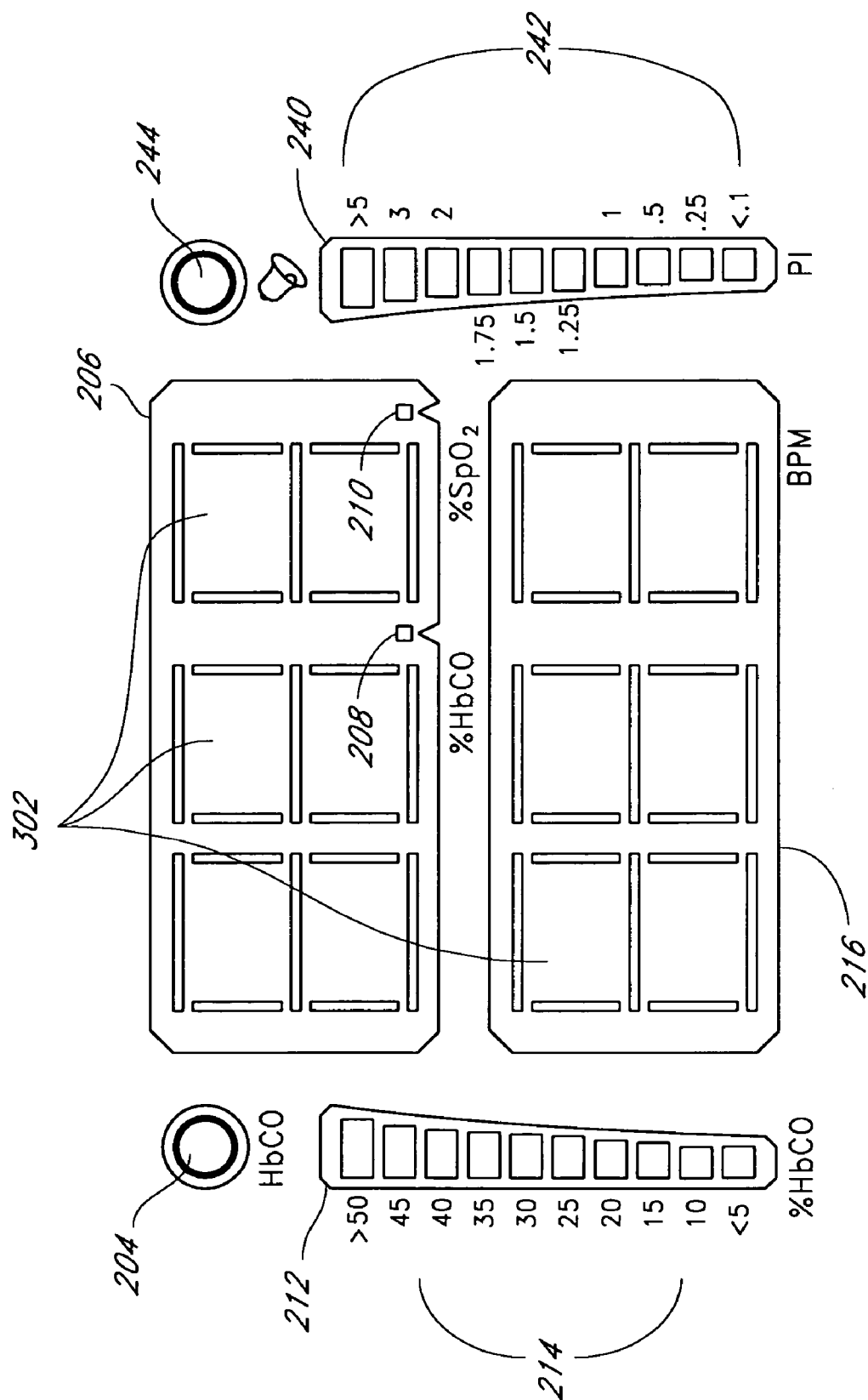


FIG. 3

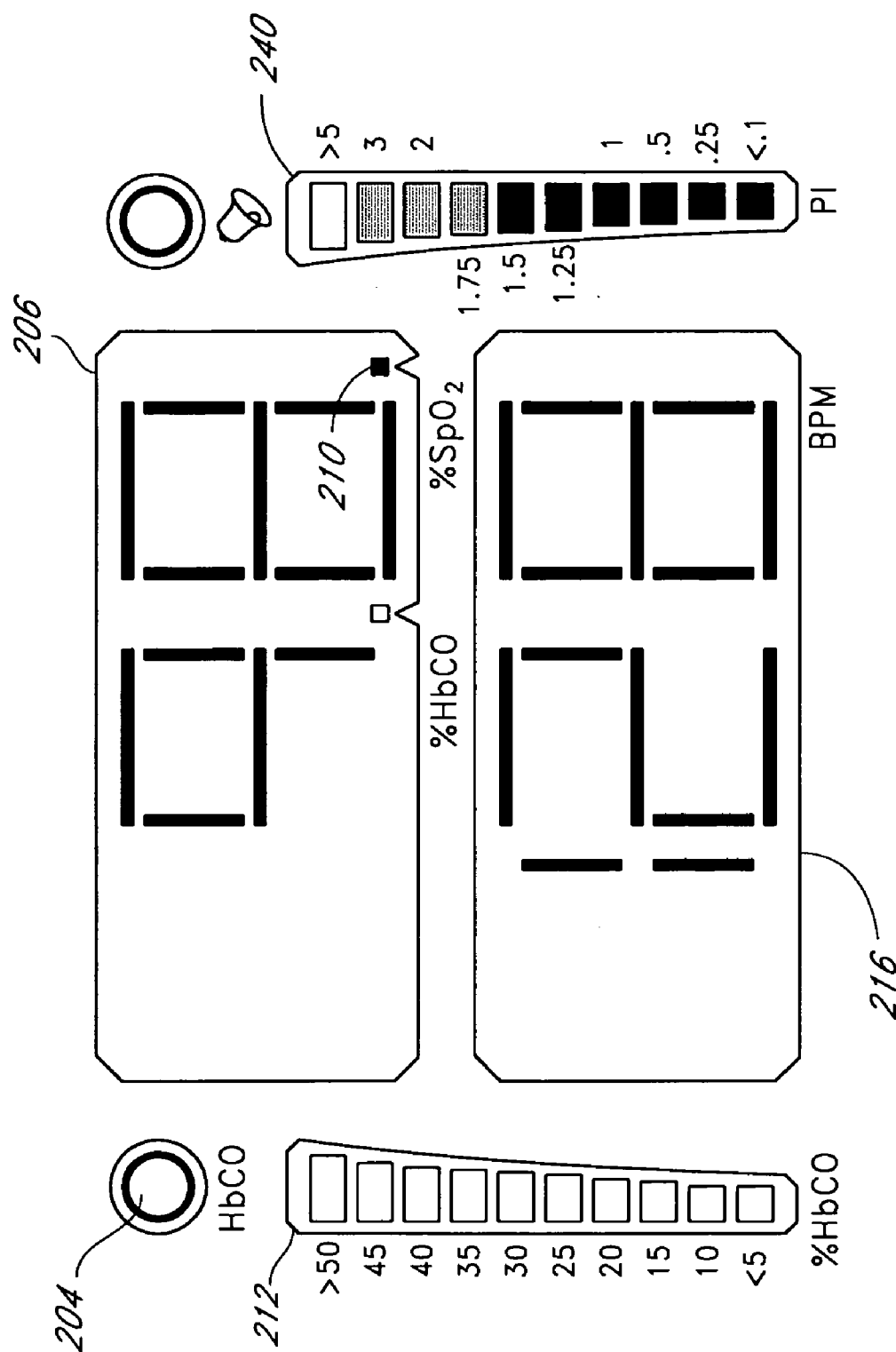


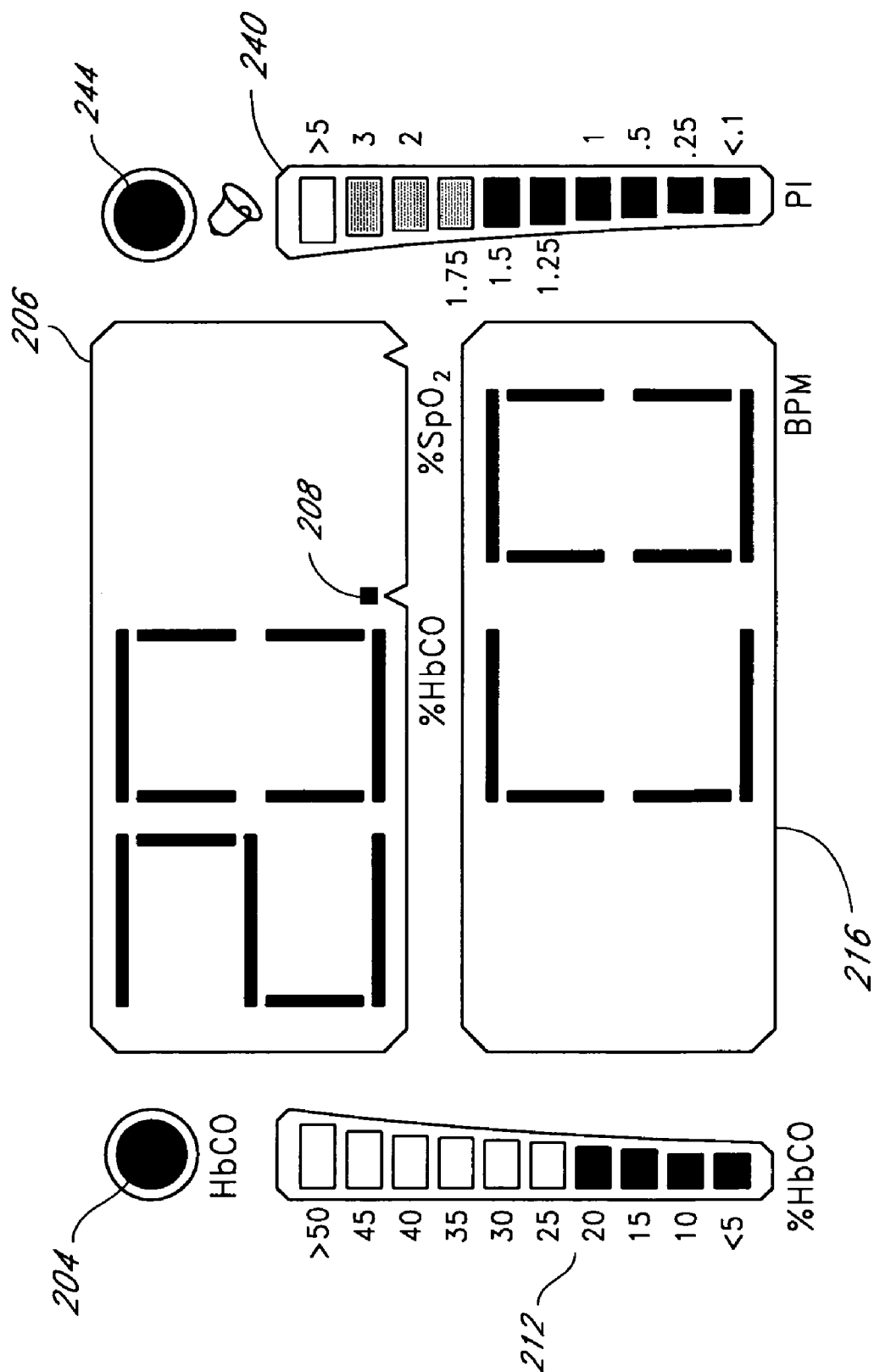
FIG. 4

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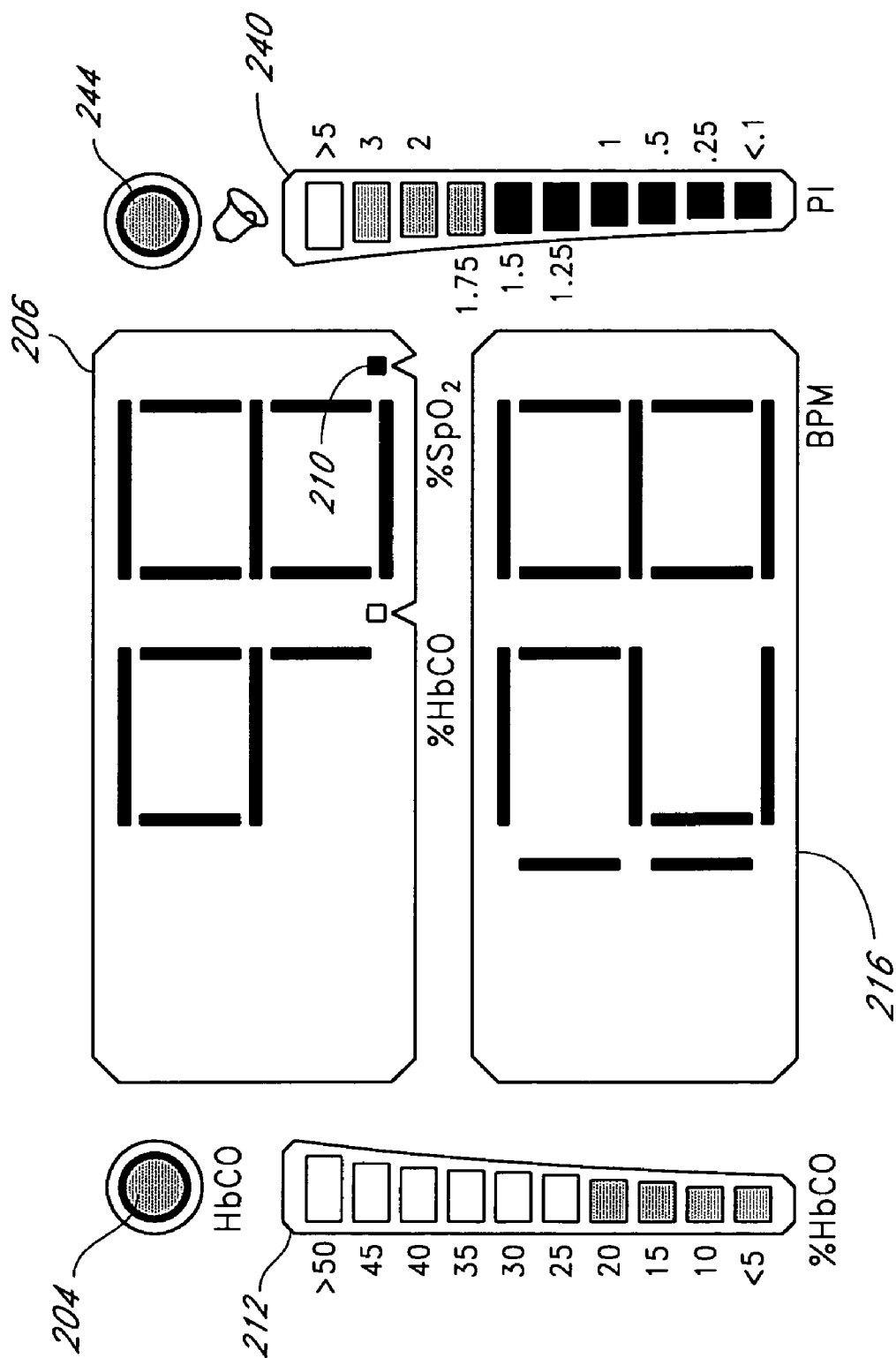


FIG. 6

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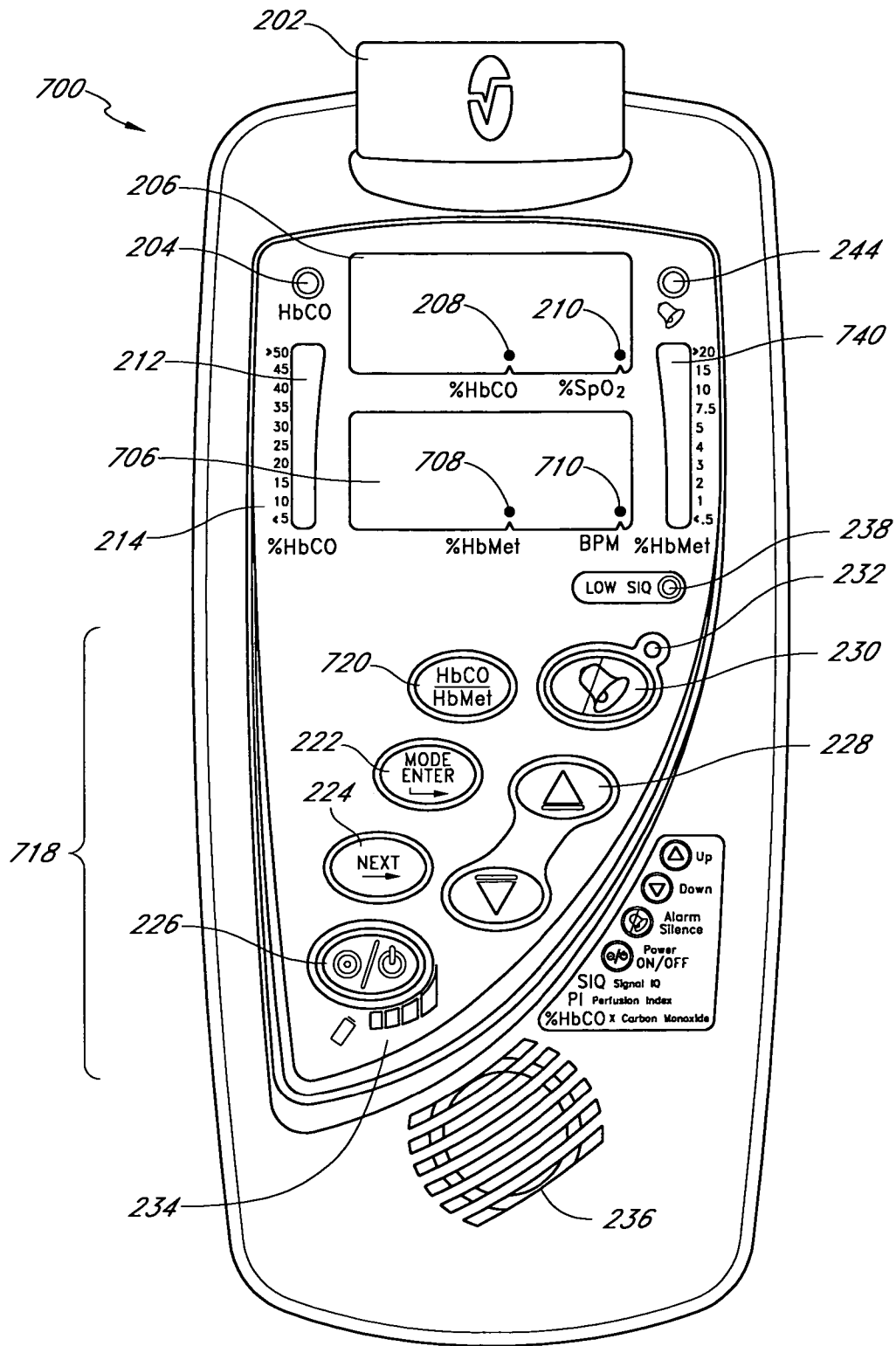


FIG. 7

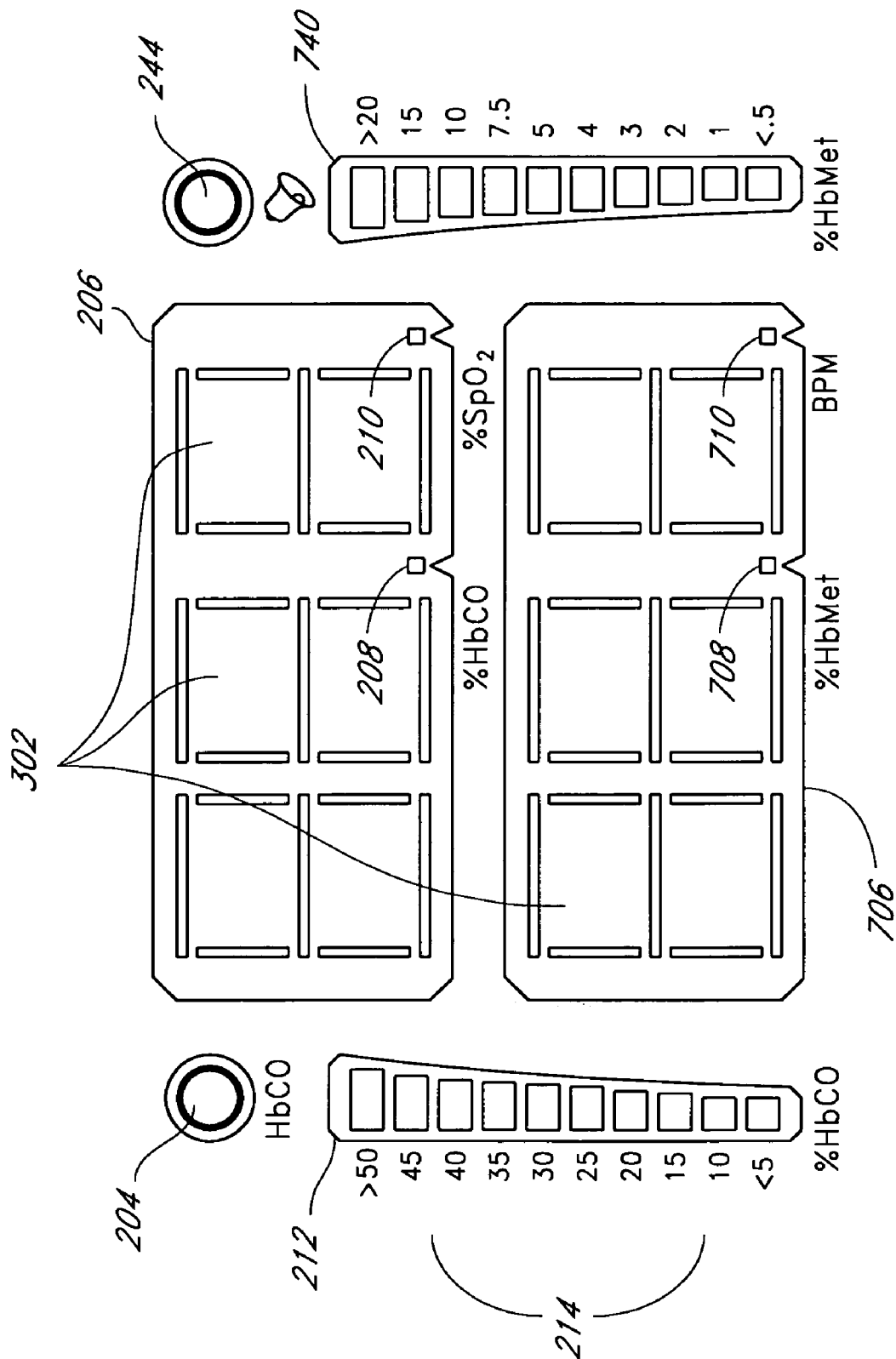


FIG. 8

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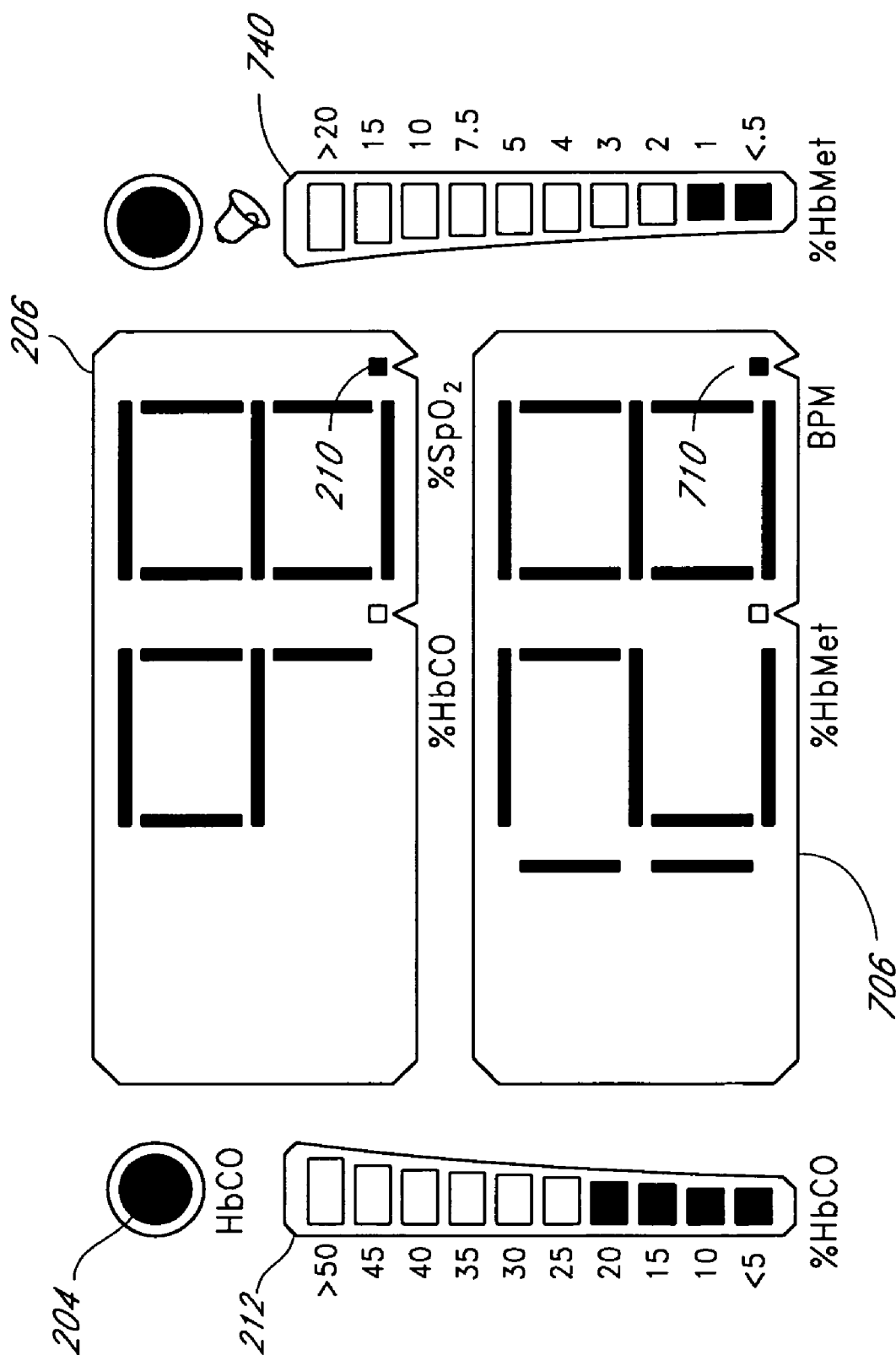


FIG. 9

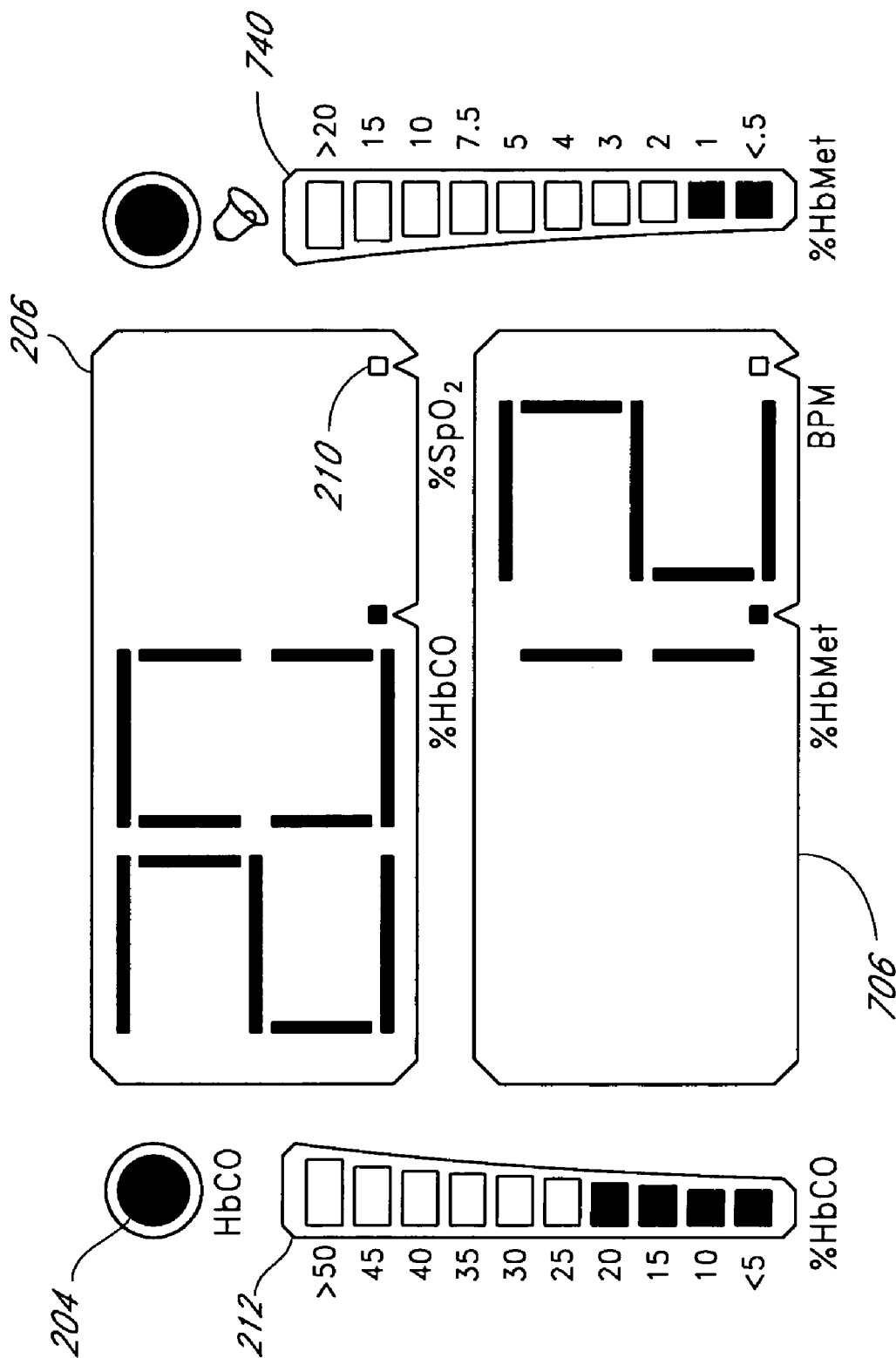


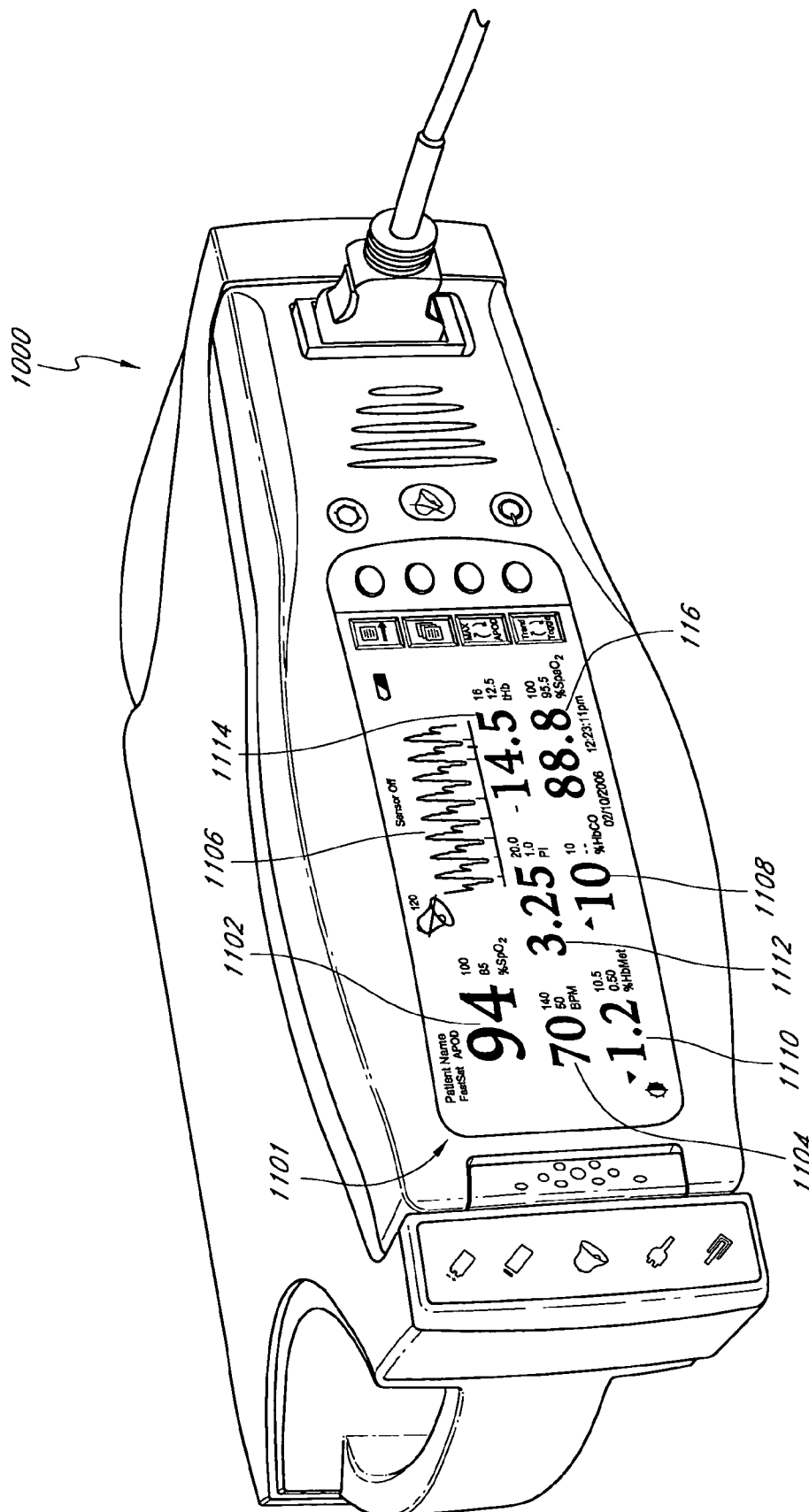
FIG. 10

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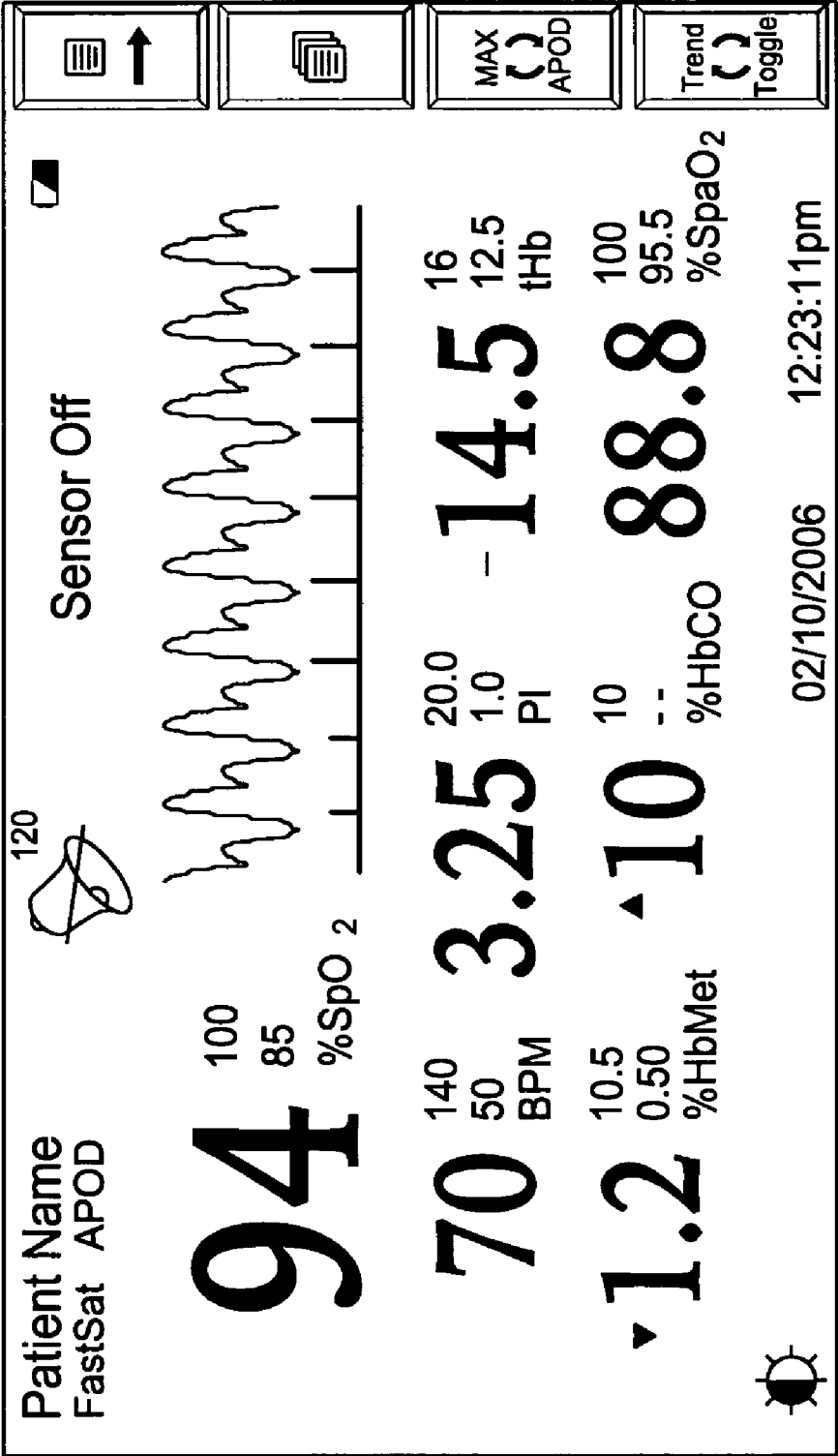
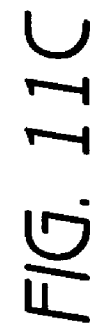


FIG. 11B



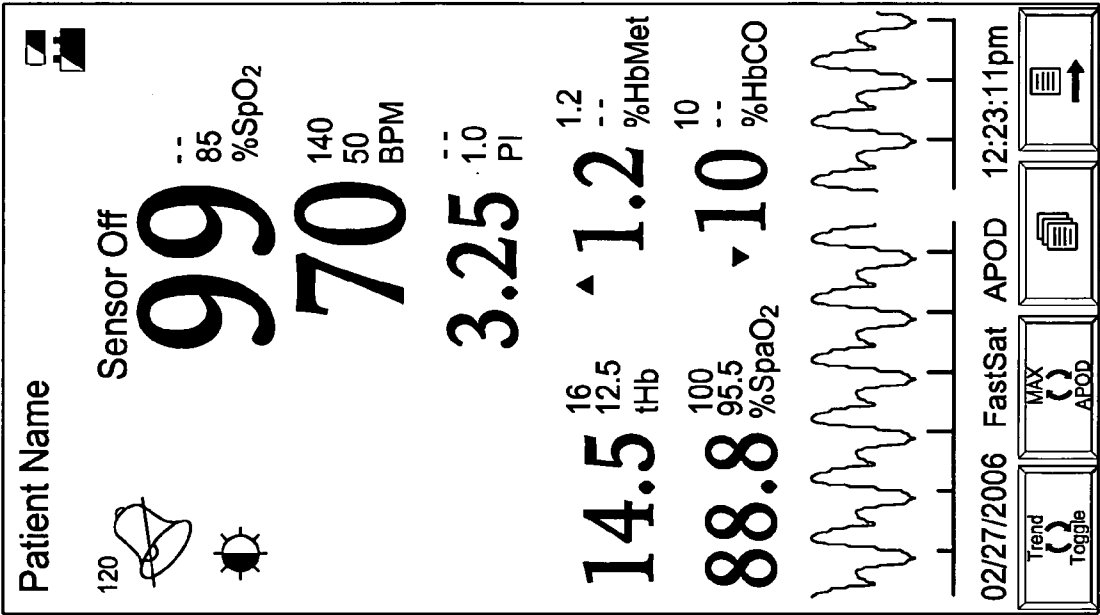


FIG. 11D

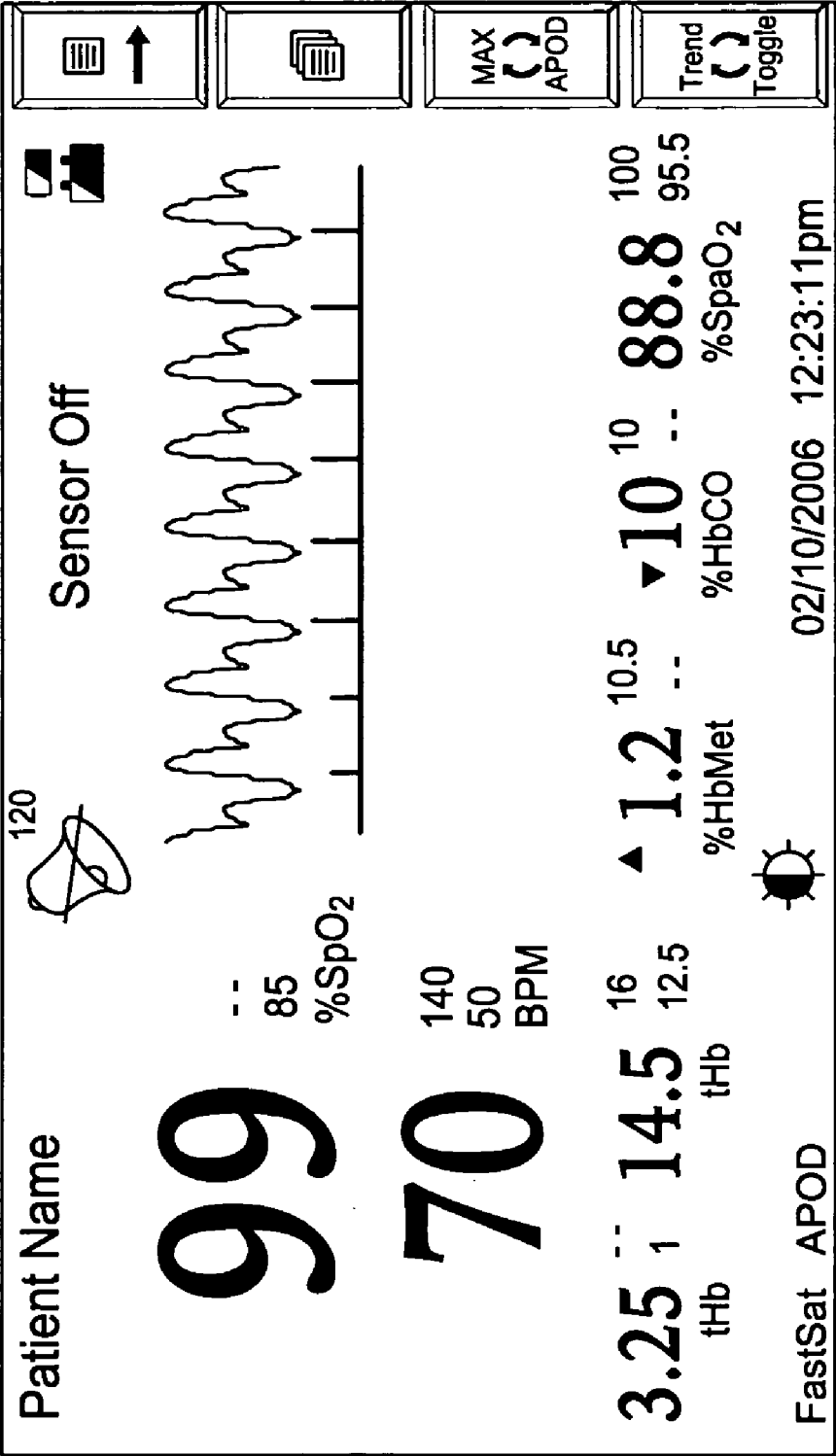


FIG. 11E

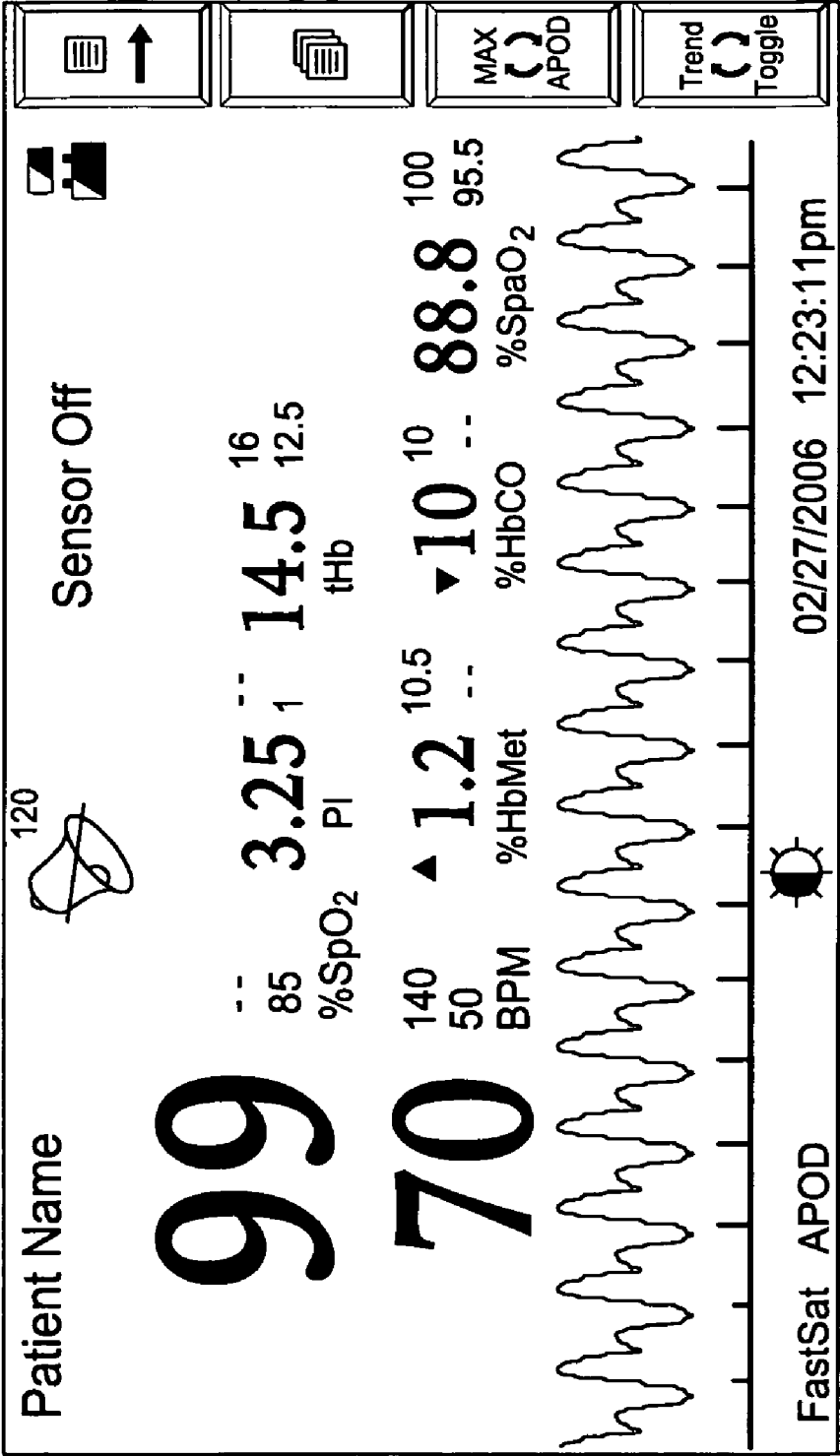


FIG. 11F

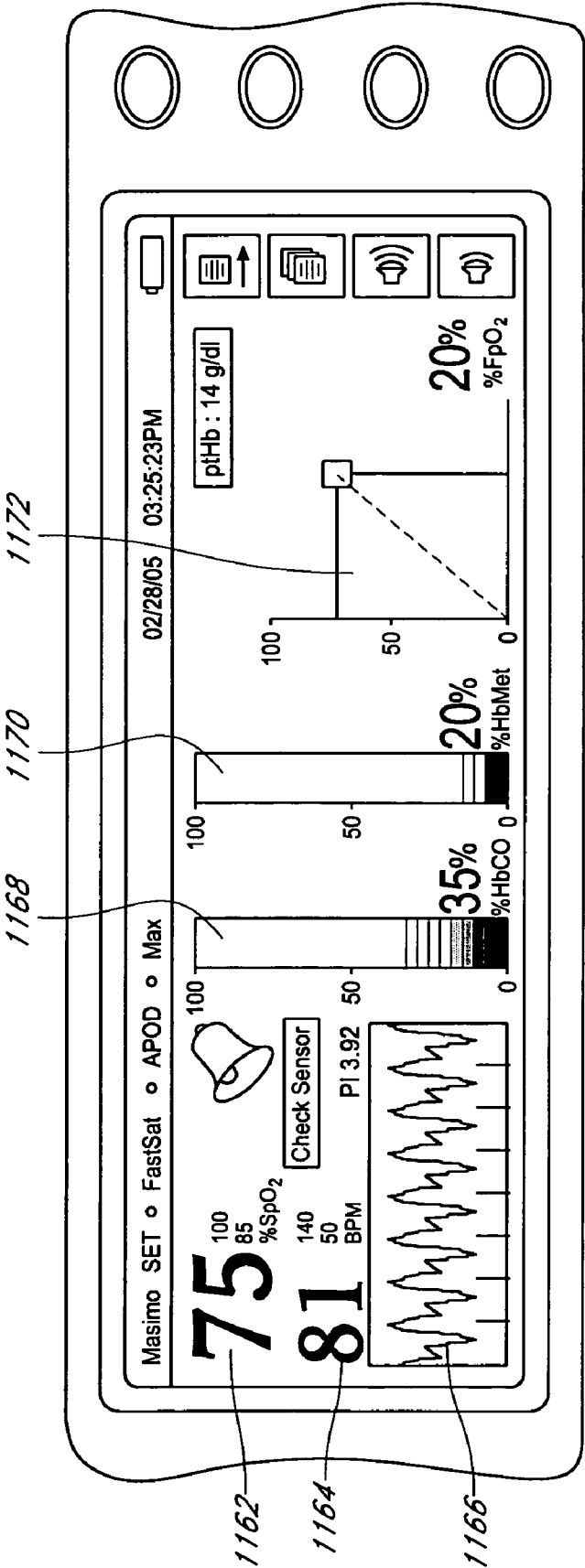


FIG. 11G

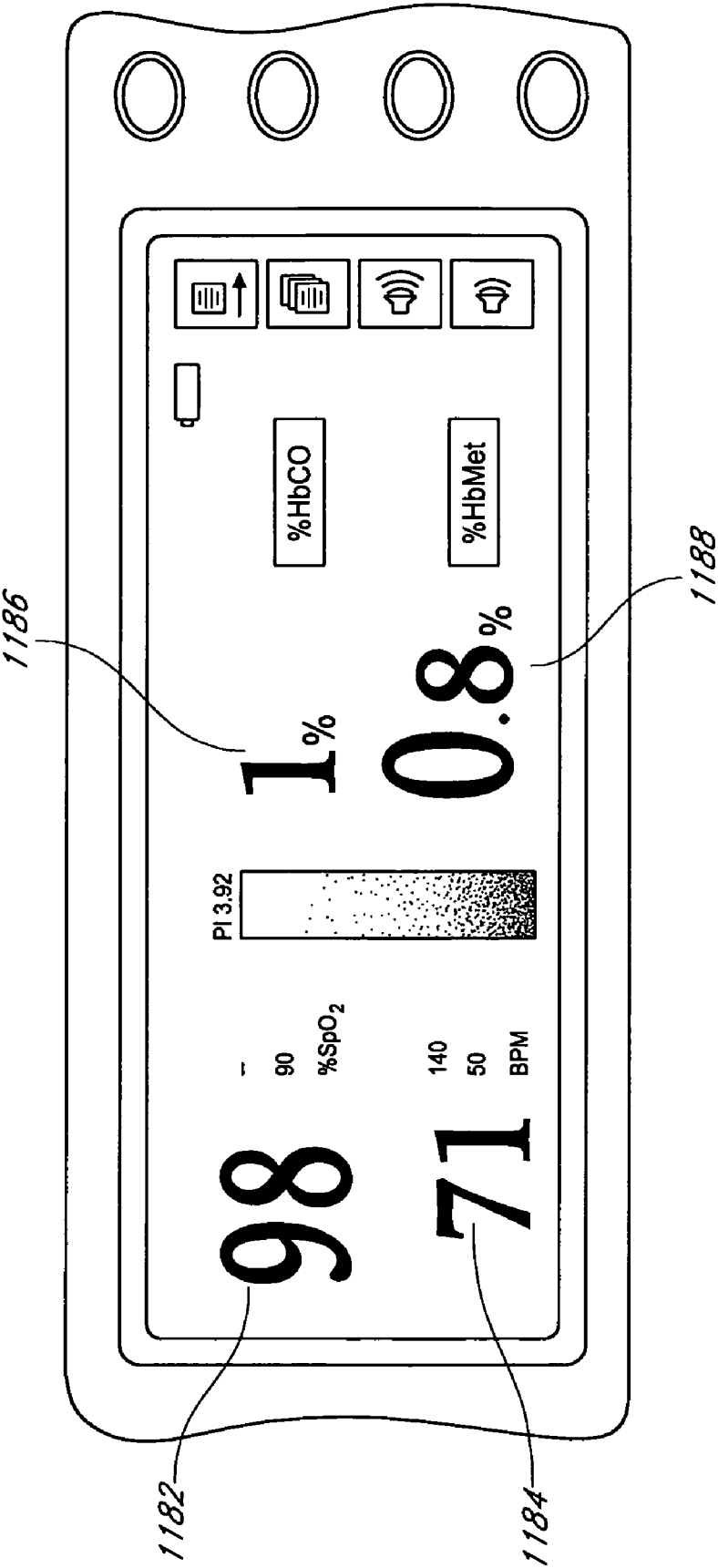


FIG. 11H

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**NONINVASIVE MULTI-PARAMETER
PATIENT MONITOR**

**PRIORITY CLAIM TO RELATED PROVISIONAL
APPLICATIONS**

The present application claims priority benefit under 35 U.S.C. §119(e) to U.S. Provisional Patent Application Ser. No. 60/657,596, filed Mar. 1, 2005, entitled “Multiple Wavelength Sensor,” No. 60/657,281, filed Mar. 1, 2005, entitled “Physiological Parameter Confidence Measure,” No. 60/657,268, filed Mar. 1, 2005, entitled “Configurable Physiological Measurement System,” and No. 60/657,759, filed Mar. 1, 2005, entitled “Noninvasive Multi-Parameter Patient Monitor.” The present application incorporates the foregoing disclosures herein by reference.

**INCORPORATION BY REFERENCE OF
RELATED UTILITY APPLICATIONS**

The present application is related to the following copending U.S. utility applications:

	App. Sr. No.	Filing Date	Title	Atty Dock.
1	11/367,013	Mar. 1, 2006	Multiple Wavelength Sensor Emitters	MLR.002A
2	11/366,995	Mar. 1, 2006	Multiple Wavelength Sensor Equalization	MLR.003A
3	11/366,209	Mar. 1, 2006	Multiple Wavelength Sensor Substrate	MLR.004A
4	11/366,210	Mar. 1, 2006	Multiple Wavelength Sensor Interconnect	MLR.005A
5	11/366,833	Mar. 1, 2006	Multiple Wavelength Sensor Attachment	MLR.006A
6	11/366,997	Mar. 1, 2006	Multiple Wavelength Sensor Drivers	MLR.009A
7	11/367,034	Mar. 1, 2006	Physiological Parameter Confidence Measure	MLR.010A
8	11/367,036	Mar. 1, 2006	Configurable Physiological Measurement System	MLR.011A
9	11/367,014	Mar. 1, 2006	Noninvasive Multi-Parameter Patient Monitor	MLR.013A
10	11/366,208	Mar. 1, 2006	Noninvasive Multi-Parameter Patient Monitor	MLR.014A

The present application incorporates the foregoing disclosures herein by reference.

FIELD OF THE DISCLOSURE

The present disclosure relates to the field of noninvasive patient monitors. More specifically, the disclosure relates to monitors displaying measurements derived using signals from optical sensors.

BACKGROUND

Spectroscopy is a common technique for measuring the concentration of organic and some inorganic constituents of a solution. The theoretical basis of this technique is the Beer-Lambert law, which states that the concentration c_i of an absorbent in solution can be determined by the intensity of light transmitted through the solution, knowing the path-length d_λ , the intensity of the incident light $I_{0,\lambda}$, and the

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extinction coefficient $\epsilon_{i,\lambda}$ at a particular wavelength λ . In generalized form, the Beer-Lambert law is expressed as:

$$I_\lambda = I_{0,\lambda} e^{-d_\lambda \mu_{0,\lambda}} \quad (1)$$

$$\mu_{0,\lambda} = \sum_{i=1}^n \epsilon_{i,\lambda} \cdot c_i \quad (2)$$

where $\mu_{0,\lambda}$ is the bulk absorption coefficient and represents the probability of absorption per unit length. The minimum number of discrete wavelengths that are required to solve Equations 1-2 are the number of significant absorbers that are present in the solution.

A practical application of this technique is pulse oximetry, which utilizes a noninvasive sensor to measure oxygen saturation (SpO_2) and pulse rate. In general, the sensor has light emitting diodes (LEDs) that transmit optical radiation of red and infrared wavelengths into a tissue site and a detector that responds to the intensity of the optical radiation after absorption (e.g., by transmission or transreflectance) by pulsatile arterial blood flowing within the tissue site. Based on this response, a processor determines measurements for SpO_2 , pulse rate, and can output representative plethysmographic waveforms. Thus, “pulse oximetry” as used herein encompasses its broad ordinary meaning known to one of skill in the art, which includes at least those noninvasive procedures for measuring parameters of circulating blood through spectroscopy. Moreover, “plethysmograph” as used herein (commonly referred to as “photoplethysmograph”), encompasses its broad ordinary meaning known to one of skill in the art, which includes at least data representative of a change in the absorption of particular wavelengths of light as a function of the changes in body tissue resulting from pulsing blood.

Pulse oximeters capable of reading through motion induced noise are available from Masimo Corporation (“Masimo”) of Irvine, Calif. Moreover, portable and other oximeters capable of reading through motion induced noise are disclosed in at least U.S. Pat. Nos. 6,770,028, 6,658,276, 6,157,850, 6,002,952, and 5,769,785. Read which are owned by Masimo, and are incorporated by reference herein. Such reading through motion oximeters have gained rapid acceptance in a wide variety of medical applications, including surgical wards, intensive care and neonatal units, general wards, home care, physical training, and virtually all types of monitoring scenarios.

SUMMARY OF THE DISCLOSURE

Despite the success of read through motion oximeter systems, there is a need to provide patient monitors capable of displaying multiple physiological parameters, other than or in addition to SpO_2 , plethysmograph waveforms, or pulse rates. For example, in accessing a patient’s condition, caregivers often desire knowledge of other blood constituents, including for example, a percent value for arterial carbon monoxide saturation (“HbCO”) or a percent value for methemoglobin saturation (“HbMet”) or the like. For example, in an embodiment, the display advantageously displays one or more of the following: pulse rate, plethysmograph waveform data, perfusion index, values of blood constituents in body tissue, including for example, HbCO, HbMet, total hemoglobin (“Hbt”), arterial oxygen saturation (“ SpO_2 ”), fractional arterial oxygen saturation (“ SpaO_2 ”), or the like. In other embodiments, the monitor may advantageously and accurately determine values for one or more of HbO_2 , Hb, blood glucose,

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water, the presence or absence of therapeutic drugs (aspirin, Dapson, nitrates, or the like) or abusive/recreational drugs (methamphetamine, alcohol, steroids, or the like), concentrations of carbon dioxide ("CO₂") or oxygen ("O"), ph levels, bilirubin, perfusion quality, signal quality or the like. Accordingly, the present disclosure includes a multi-parameter patient monitor capable of determining one or more of the foregoing parameters, other than or in addition to, SpO₂, plethysmograph waveforms, or perfusion quality index.

In an embodiment, the display of a noninvasive multi-parameter patient monitor advantageously includes a plurality of display modes enabling more parameter data to be displayed than the available physical display area or real estate. In an embodiment, a user may cycle different parameter values through an area of the display common to both parameters even when one parameter is shifted, through, for example, actuation of a user input key. The patient monitor may also display different parameters as color-coded. For example, when the following measured parameters are within "normal" ranges, SpO₂ may be displayed red, pulse rate (BPM) may be displayed green, HbCO may be displayed orange, HbMet may be displayed blue, or the like. In an embodiment, measured values of SpO₂ may be displayed in white, BPM may be displayed in yellow green or aquamarine, P_{ITM} may be displayed in violet, Hbt may be displayed in grass green, HbMet may be displayed in blue or light blue, HbCO may be displayed in orange, and SpaO₂ may be displayed in electric blue.

Moreover, parameter trend data may also be displayed using the same or similar color coding, especially when multiple trends are displayed on one or more display graphs. In addition, more coarse or gross parameter indications may be displayed for quick reference to indicate to a caregiver whether any of a variety of monitored parameters, such as, for example, SpO₂, HbCO or HbMet is within acceptable ranges. The monitor may advantageously include additional display information, such as, for example, parametric displays where one parameter is displayed as a function of another, three dimensional displays (for example, extending a parametric display along time or an additional parameter), directional indicators predicting where a parameter is likely heading or reporting a general direction a parameters has been trending, or the like.

In addition to the foregoing, caregivers often desire to more closely monitor parameters that are close to, approaching, or beyond normal safe thresholds. In an embodiment, the patient monitor provides an indication that the caregiver should change display modes to view more critical monitored parameters. In alternative embodiments, the patient monitor automatically changes display modes to show parameters moving closer to or beyond normal thresholds.

In an embodiment, the patient monitor includes an audible or visual indication of a type of sensor communicating with the monitor. For example, the monitor may determine how many wavelengths a particular attached sensor will emit through communication with memory devices associated with the attached sensor or cable.

Additional embodiments include audio or visual alarms for each of multiple monitored parameters, combinations of parameters, an indication of perfusion in the tissue of the measurement site, an indication of the confidence the signal processing has in its output measurements, or the like.

For purposes of summarization, certain aspects, advantages and novel features are described herein. Of course, it is to be understood that not necessarily all such aspects, advantages or features need to be present in any particular embodiment.

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BRIEF DESCRIPTION OF THE DRAWINGS

The drawings and the associated descriptions are provided to illustrate embodiments of the disclosure and not to limit the scope of the claims.

FIG. 1 illustrates a block diagram of an exemplary embodiment of a patient monitoring system including a sensor and a multi-parameter patient monitor.

FIG. 2 illustrates a top elevation view of an exemplary handheld noninvasive multi-parameter patient monitor capable of displaying at least HbCO, such as, for example, the patient monitor of FIG. 1.

FIG. 3 illustrates an exemplary display of the patient monitor of FIG. 2.

FIG. 4 illustrates the display of FIG. 3 showing measured values of SpO₂, BPM, perfusion, and type of sensor according to an exemplary embodiment of the patient monitor of FIG. 1.

FIG. 5 illustrates the display of FIG. 3 showing measured values of HbCO, perfusion, and type of sensor according to an exemplary embodiment of the patient monitor of FIG. 1.

FIG. 6 illustrates the display of FIG. 3 showing measured values of SpO₂, HbCO, BPM, perfusion, and type of sensor, according to an exemplary embodiment of the patient monitor of FIG. 1.

FIG. 7 illustrates a top elevation view of an exemplary handheld noninvasive multi-parameter patient monitor capable of displaying at least HbCO and HbMet, such as, for example, the patient monitor of FIG. 1.

FIG. 8 illustrates an exemplary display of the patient monitor of FIG. 7.

FIG. 9 illustrates the display of FIG. 8 showing measured values of SpO₂, BPM, HbCO, HbMet, and type of sensor according to an exemplary embodiment of the patient monitor of FIG. 1.

FIG. 10 illustrates the display of FIG. 8 showing measured values of HbCO, HbMet, and type of sensor according to an exemplary embodiment of the patient monitor of FIG. 1.

FIG. 11A illustrates a perspective view of an exemplary noninvasive multi-parameter patient monitor such as, for example, the patient monitor of FIG. 1.

FIGS. 11B-11H illustrate display screens of the patient monitor of FIG. 11A.

DETAILED DESCRIPTION OF PREFERRED AND ALTERNATIVE EMBODIMENTS

Embodiments of the present disclosure include a portable or other multi-parameter patient monitor capable of determining multiple physiological parameters from one or more signals output from one or more light sensitive detectors capable of detecting light attenuated by body tissue carrying pulsing blood. For example, in an embodiment, the monitor advantageously and accurately determines a wide variety of physiological parameters or other calculations as discussed above.

In an embodiment, the display of patient monitor advantageously includes a plurality of display modes enabling more parameter data to be displayed than the available physical display real estate. For example, the patient monitor may include one or more user input keys capable of toggling through measurement data. In an embodiment, the displays include mode indicators providing caregivers easily identifiable visual queues, such as LED's, text, icons, or other indicia providing readily identifiable queues as to which parameter is being displayed. In an embodiment, the display may shift, may be parameter color-coded, or the like to further ensure

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quick comprehension of which measured parameter is the displayed parameter. For example, in an embodiment, the monitor displays SpO₂ in white, pulse rate (BPM) in green, HbCO in orange, and HbMet in blue when the respective measured parameter is within a “normal” range.

In an embodiment, the patient monitor provides an indication that the caregiver should change display modes to view more critical or time sensitive measured parameters, specific caregiver selected parameters, or the like. For example, the patient monitor may advantageously sound audio or visual alarms that alert the caregiver to particular one or more of worsening parameters, parameters changing in a predetermined pattern or rate, parameters stabilizing below user defined or safe thresholds, caregiver selected parameters, or the like. The monitor may also use alerts that provide audio or visual indications of the severity of the condition, severity of the change, or the like. In alternative embodiments, the patient monitor may automatically change display modes when a particular parameter crosses one or more thresholds. For example, a patient monitor may be displaying a first parameter, such as a plethysmograph, and upon determining measurements indicating that HbMet is trending toward an alarm condition, the monitor may automatically switch from displaying the first parameter to the alarming parameter, or in this case, a trend of the alarming parameter.

In an embodiment, a switch is provided to allow a user to switch displays to view an alarming measurement. In an embodiment, during an alarm condition, a parameter display may switch to a trend graph in the same or different color, line weight, flash, flash rate, intensity, size, or the like.

The patient monitor may also include one or more displays capable of displaying trend data for any one or more of the monitored or derived patient parameters. For example, the trend data may be displayed in graph form, may include multiple trend lines, each representing a different monitored or derived patient parameter. Moreover, each trend line may be color-coded to facilitate quick comprehension of which trend line represents which measured parameter. However, an artisan will recognize from the disclosure herein a large number of identification techniques including color-coding, identifying text, or the like. Additionally, user input may toggle displayed trend data, may select which parameters to display simultaneously, or the like.

In an embodiment, the patient monitor includes an audible or visual indication of a type of sensor communicating with the monitor. For example, the patient monitor may provide a particular audio or visual indication, such as a beep, LED activation, graphic activation, text messages, voice messages, or the like, to indicate communication with or connection to an approved sensor, patient cable, combination, or the like. In an embodiment, the indication may change based on the manufacturer, type of sensor recognized or not recognized, type of patient, type of physiological parameters measurable with the attached sensor, or the like. Additional embodiments include an indication of perfusion in the tissue of the measurement site and an indication of the confidence the signal processing has in its output measurements or input signal quality.

To facilitate an understanding of the disclosure, the remainder of the description references exemplary embodiments illustrated in the drawings. Moreover, in this application, reference is made to many blood parameters. Some references that have common shorthand designations are referenced through such shorthand designations. For example, as used herein, HbCO designates carboxyhemoglobin, HbMet designates methemoglobin, and Hbt designates total hemoglobin. Other shorthand designations such as COHb,

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MetHb, and tHb are also common in the art for these same constituents. These constituents are generally reported herein in terms of a percentage, often referred to as saturation, relative concentration or fractional saturation. Total hemoglobin is generally reported as a concentration in g/dL. The use of the particular shorthand designators presented in this application does not restrict the term to any particular manner in which the designated constituent is reported.

FIG. 1 illustrates a block diagram of an exemplary embodiment of a patient monitoring system **100**. As shown in FIG. 1, the system **100** includes a patient monitor **102** comprising a processing board **104** and a host instrument **108**. The processing board **104** communicates with a sensor **106** to receive one or more intensity signal(s) indicative of one or more parameters of tissue of a patient. The processing board **104** also communicates with a host instrument **108** to display determined values calculated using the one or more intensity signals. According to an embodiment, the board **104** comprises processing circuitry arranged on one or more printed circuit boards capable of installation into the monitor **102**, or capable of being distributed as some or all of one or more OEM components for a wide variety of host instruments monitoring a wide variety of patient information. In an embodiment, the processing board **102** comprises a sensor interface **110**, a digital signal processor and signal extractor (“DSP” or “processor”) **112**, and an instrument manager **114**. In general, the sensor interface **110** converts digital control signals into analog drive signals capable of driving sensor emitters, and converts composite analog intensity signal(s) from light sensitive detectors into digital data.

In an embodiment, the sensor interface **110** manages communication with external computing devices. For example, in an embodiment, a multipurpose sensor port (or input/output port) is capable of connecting to the sensor **106** or alternatively connecting to a computing device, such as a personal computer, a PDA, additional monitoring equipment or networks, or the like. When connected to the computing device, the processing board **104** may upload various stored data for, for example, off-line analysis and diagnosis. The stored data may comprise trend data for any one or more of the measured parameter data, plethysmograph waveform data acoustic sound waveform, or the like. Moreover, the processing board **104** may advantageously download from the computing device various upgrades or executable programs, may perform diagnosis on the hardware or software of the monitor **102**. In addition, the processing board **104** may advantageously be used to view and examine patient data, including raw data, at or away from a monitoring site, through data uploads/downloads, or network connections, combinations, or the like, such as for customer support purposes including software maintenance, customer technical support, and the like. Upgradable sensor ports are disclosed in copending U.S. application Ser. No. 10/898,680, filed on Jul. 23, 2004, titled “Multipurpose Sensor Port,” incorporated by reference herein.

As shown in FIG. 1, the digital data is output to the DSP **112**. According to an embodiment, the DSP **112** comprises a processing device based on the Super Harvard ARChitecture (“SHARC”), such as those commercially available from Analog Devices. However, a skilled artisan will recognize from the disclosure herein that the DSP **112** can comprise a wide variety of data and/or signal processors capable of executing programs for determining physiological parameters from input data. In particular, the DSP **112** includes program instructions capable of receiving multiple channels of data related to one or more intensity signals representative of the absorption (from transmissive or reflective sensor systems) of

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a plurality of wavelengths of emitted light by body tissue. In an embodiment, the DSP **112** accepts data related to the absorption of eight (8) wavelengths of light, although an artisan will recognize from the disclosure herein that the data can be related to the absorption of two (2) to sixteen (16) or more wavelengths.

FIG. **1** also shows the processing board **104** including the instrument manager **114**. According to an embodiment, the instrument manager **114** may comprise one or more micro-controllers controlling system management, including, for example, communications of calculated parameter data and the like to the host instrument **108**. The instrument manager **114** may also act as a watchdog circuit by, for example, monitoring the activity of the DSP **112** and resetting it when appropriate.

The sensor **106** may comprise a reusable clip-type sensor, a disposable adhesive-type sensor, a combination sensor having reusable and disposable components, or the like. Moreover, an artisan will recognize from the disclosure herein that the sensor **106** can also comprise mechanical structures, adhesive or other tape structures, Velcro wraps or combination structures specialized for the type of patient, type of monitoring, type of monitor, or the like. In an embodiment, the sensor **106** provides data to the board **104** and vice versa through, for example, a patient cable. An artisan will also recognize from the disclosure herein that such communication can be wireless, over public or private networks or computing systems or devices, or the like.

As shown in FIG. **1**, the sensor **106** includes a plurality of emitters **116** irradiating the body tissue **118** with differing wavelengths of light, and one or more detectors **120** capable of detecting the light after attenuation by the tissue **118**. In an embodiment, the emitters **116** comprise a matrix of eight (8) emission devices mounted on a flexible substrate, the emission devices being capable of emitting eight (8) differing wavelengths of light. In other embodiments, the emitters **116** may comprise twelve (12) or sixteen (16) emitters, although other numbers of emitters are contemplated, including two (2) or more emitters. As shown in FIG. **1**, the sensor **106** may include other electrical components such as, for example, a memory device **122** comprising an EPROM, EEPROM, ROM, RAM, microcontroller, combinations of the same, or the like. In an embodiment, other sensor components may include a temperature determination device **123** or other mechanisms for, for example, determining real-time emission wavelengths of the emitters **116**.

The memory **122** may advantageously store some or all of a wide variety data and information, including, for example, information on the type or operation of the sensor **106**; type or identification of sensor buyer or distributor or groups of buyer or distributors, sensor manufacturer information, sensor characteristics including the number of emitting devices, the number of emission wavelengths, data relating to emission centroids, data relating to a change in emission characteristics based on varying temperature, history of the sensor temperature, current, or voltage, emitter specifications, emitter drive requirements, demodulation data, calculation mode data, the parameters for which the sensor is capable of supplying sufficient measurement data (e.g., HpCO, HpMet, HbT, or the like), calibration or parameter coefficient data, software such as scripts, executable code, or the like, sensor electronic elements, whether the sensor is a disposable, reusable, multi-site, partially reusable, partially disposable sensor, whether it is an adhesive or non-adhesive sensor, whether the sensor is a reflectance, transmittance, or transreflectance sensor, whether the sensor is a finger, hand, foot, forehead, or ear sensor, whether the sensor is a stereo sensor or a two-headed

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sensor, sensor life data indicating whether some or all sensor components have expired and should be replaced, encryption information, keys, indexes to keys or hash functions, or the like, monitor or algorithm upgrade instructions or data, some or all of parameter equations, information about the patient, age, sex, medications, and other information that may be useful for the accuracy or alarm settings and sensitivities, trend history, alarm history, or the like. In an embodiment, the monitor may advantageously store data on the memory device, including, for example, measured trending data for any number of parameters for any number of patients, or the like, sensor use or expiration calculations, sensor history, or the like.

FIG. **1** also shows the patient monitor **102** including the host instrument **108**. In an embodiment, the host instrument **108** communicates with the board **104** to receive signals indicative of the physiological parameter information calculated by the DSP **112**. The host instrument **108** preferably includes one or more display devices **124** capable of displaying indicia representative of the calculated physiological parameters of the tissue **118** at the measurement site. In an embodiment, the host instrument **108** may advantageously comprise a handheld housing capable of displaying one or more of a pulse rate, plethysmograph data, perfusion quality such as a perfusion quality index ("PITM"), signal or measurement quality ("SQ"), values of blood constituents in body tissue, including for example, SpO₂, HbCO, HbMet, Hbt, or the like. In other embodiments, the host instrument **108** is capable of displaying values for one or more of Hbt, Hb, blood glucose, bilirubin, or the like. The host instrument **108** may be capable of storing or displaying historical or trending data related to one or more of the measured values, combinations of the measured values, plethysmograph data, or the like. The host instrument **108** also includes an audio indicator **126** and user input device **128**, such as, for example, a keypad, touch screen, pointing device, voice recognition device, or the like.

In still additional embodiments, the host instrument **108** includes audio or visual alarms that alert caregivers that one or more physiological parameters are falling below predetermined safe thresholds. The host instrument **108** may include indications of the confidence a caregiver should have in the displayed data. In a further embodiment, the host instrument **108** may advantageously include circuitry capable of determining the expiration or overuse of components of the sensor **106**, including, for example, reusable elements, disposable elements, or combinations of the same.

Although described in terms of certain embodiments, other embodiments or combination of embodiments will be apparent to those of ordinary skill in the art from the disclosure herein. For example, the monitor **102** may comprise one or more monitoring systems monitoring parameters, such as, for example, vital signs, blood pressure, ECG or EKG, respiration, glucose, bilirubin, or the like. Such systems may combine other information with intensity-derived information to influence diagnosis or device operation. Moreover, the monitor **102** may advantageously include an audio system, preferably comprising a high quality audio processor and high quality speakers to provide for voiced alarms, messaging, or the like. In an embodiment, the monitor **102** may advantageously include an audio out jack, conventional audio jacks, headphone jacks, or the like, such that any of the display information disclosed herein may be audibilized for a listener. For example, the monitor **102** may include an audible transducer input (such as a microphone, piezoelectric sensor, or the like) for collecting one or more of heart sounds, lung sounds, trachea sounds, or other body sounds and such

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sounds may be reproduced through the audio system and output from the monitor **102**. Also, wired or wireless communications (such as Bluetooth or WiFi, including IEEE 801.11a, b, or g), mobile communications, combinations of the same, or the like, may be used to transmit the audio output to other audio transducers separate from the monitor **102**.

For example, patterns or changes in the continuous noninvasive monitoring of intensity-derived information may cause the activation of other vital sign measurement devices, such as, for example, blood pressure cuffs.

FIG. 2 illustrates a perspective view of an exemplary handheld noninvasive multi-parameter patient monitor **200**, such as, for example, the patient monitor **102** of FIG. 2. Patient monitors **200** exhibiting combinations of many of the features described herein are advantageously commercially available from Masimo under the brand name "Rad 57c." As shown in FIG. 1, the monitor **200** includes a patient cable connector **202** capable of mechanical mating with a patient cable to establish communication between the board **104** and the sensor **106**. In an embodiment, the connector **202** comprises a multipurpose cable connector such as that disclosed in the incorporated U.S. application Ser. No. 10/898,680, titled "Multipurpose Sensor Port," disclosing communication between the board **104** and an external computing device.

The monitor **200** also comprises a HbCO indicator **204** advantageously providing a visual queue that a HbCO capable sensor is properly connected through the connector **202**. For example, the HbCO indicator **204** may advantageously activate when a sensor is connected that communicates sufficient information to determine HbCO, such as, for example, a sensor capable of emitting sufficient different wavelengths of light, a sensor storing sufficient data on the memory **122**, a sensor having appropriate encryption data or key, combinations of the same, or the like. For example, in an embodiment, the processor **112** may receive information from a memory **122** indicating a number of available LED wavelengths for the attached sensor. Based on the number of wavelengths, or other information stored on the memory **122**, the processor **112** may determine whether an HbCO-ready sensor has been attached to the monitor **200**. An artisan will also recognize from the disclosure herein that the HbCO indicator **204** may advantageously comprise a HbMet indicator, Hbt indicator, or the like, which activates to a predetermined color associated with a parameter, or any color, or deactivates the same, to convey a type of attached sensor. Moreover, the artisan will recognize from the disclosure herein other parameters that may use other sensor components and the monitor **200** may include indicators capable of indicating communication with those types of sensors.

In an embodiment, the monitor **200** may also audibly indicate the type of sensor connected. For example, the monitor **200** may emit predetermined number or frequency of beeps associated with recognition of a particular sensor, a particular manufacturer, failure to recognize the sensor, or the like. Moreover, the sensor type may be indicative of the componentry, such as, for example, whether the sensor produces sufficient data for the determination of HbCO, HbMet, Hbt and SpO₂, SpO₂ only, SpO₂ and HbMet, any combination of the foregoing or other parameters, or the like. Additionally, the sensor type may be indicative of specific sensors designed for a type of patient, type of patient tissue, or the like. In other embodiments, the monitor **200** may announce the type of connector through speaker **236**.

An artisan will also recognize from the disclosure herein that other mechanical (such as keys), electrical, or combination devices may inform the monitor **200** of the type of attached sensor. In an embodiment, the processor **112** also

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may select to drive less emitters that are currently available, such as, for example, in the presence of low noise and when power consumption is an issue.

The monitor **200** also comprises a multi-mode display **206** capable of displaying, for example, measurements of SpO₂ and HbCO (or alternatively, HbMet). In an embodiment, the display **206** has insufficient space or display real estate to display the many parameters capable of being measured by the monitor **200**. Thus, the multi-mode display **206** may advantageously cycle through two or more measured parameters in an area common to both parameters even when shifted. In such embodiments, the monitor **200** may also advantageously include parameter indicators **208**, **210**, providing additional visual queues as to which parameter is currently displayed. In an embodiment, the display may also cycle colors, flash rates, or other audio or visual queues providing readily identifiable information as to which measured parameter is displayed. For example, when the multi-mode display **206** displays measured values of SpO₂ that are normal, the numbers may advantageously appear in green, while normal measured values of HbCO may advantageously appear in orange, and normal measured values of HbMet may appear in blue. Moreover, in an embodiment, the display **206** flashes at a predefined rate when searching for saturation and at another predefined rate when a signal quality is below a predetermined threshold.

The monitor **200** also comprises a HbCO bar **212** where in an embodiment a plurality of LED's activate from a bottom toward a top such that the bar "fills" to a level proportional to the measured value. For example, the bar **212** is lowest when the dangers from carbon monoxide poisoning are the least, and highest when the dangers are the greatest. The bar **212** includes indicia **214** that provide an indication of the severity of carbon monoxide saturation in a patient's blood. As shown in FIG. 2, the bar **212** and the indicia **214** continuously indicate the concentration of HbCO in about 5% increments. The indicia **214** indicate a measurement of HbCO saturation percentage between about 0 and about 50% with a granularity of about 5%. However, an artisan will also recognize from the disclosure herein a wide variety of ranges and granularities could be used, the indicia **214** could be electronically displayed in order to straightforwardly increase or decrease resolution, or the like. For example, HbCO may advantageously be displayed with greater resolution than \pm about %5 in a lower portion of the scale. For example, an HbCO bar may advantageously include a scale of about <3%, about 6%, about 9%, about 12%, about 15%, about 20%, about 25%, about 30%, about 35%, and about >40%.

As is known in the art, carbon monoxide in the blood can lead to serious medical issues. For example and depending upon the particular physiology of a patient, about 10% carbon monoxide saturation can lead to headaches, about 20% can lead to throbbing headaches, or dyspnea on exertion, about 30% can lead to impaired judgment, nausea, dizziness and/or vomiting, visual disturbance, or fatigue, about 40% can lead to confusion and syncope, and about 50% and above can lead to comas, seizures, respiratory failure and even death.

In an embodiment, the bar **212** is the same or similar color as the multi-mode display **206** when displaying HbCO. In other embodiments, the bar **212** is lowest and green when the dangers from carbon monoxide poisoning are the least, and highest and red when the dangers are the greatest. In an embodiment, as HbCO increases, the entire bar **212** may advantageously change color, such as, for example, from green to red, to provide a clear indication of deepening severity of the condition. In other embodiments, the bar **212** may advantageously blink or flash, an audio alarm may beep or

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provide a continuation or rise in pitch or volume, or the like to alert a caregiver of deepening severity. Moreover, straightforward to complex alarm rules may be implemented to reduce false alarms based on, for example, knowledge of the physiological limitations on the rate of change in HbCO or the like.

Additionally, the monitor **200** may be capable of storing and outputting historical parameter data, display trend traces or data, or the like. Although the foregoing bar **212** has been described in terms of certain preferred embodiments, other embodiments will be apparent to those of ordinary skill in the art from the disclosure herein.

FIG. **2** also shows the monitor **200** including a pulse display **216** displaying measured pulse rate in beats per minute ("BPM"). In an embodiment, the display **212** flashes when searching for a pulse. The pulse display **216** advantageously displays measured pulse rates from about zero (0) to about two hundred and forty (240) BPM. Moreover, when the measured pulse rates are considered normal, the pulse display **216** is advantageously green. Similar to other displays associated with the monitor **200**, the pulse display **216** may employ a variety of color changes, audio alarms, or combinations of the same to indicate measured BPM below predetermined safe thresholds. In an embodiment, the pulse rate display **216** displays the measured pulse rate during the display of SpO₂ and displays message data during the display of other parameters. For example, during the display of HbCO, the display **216** may advantageously display the term "CO." In an embodiment, the display of the message data may be in the same or similar color as the other displays. For example, in an embodiment, the multi-mode display **206**, the bar **212**, and the pulse display **216** may all display data or messages in orange when the multi-mode display **206** displays measured HbCO values.

FIG. **2** also illustrates the monitor **200** comprising user input keys **218**, including a HbCO button **220**, mode/enter button **222**, next button **224**, power on/off button **226**, up/down button **228**, and alarm silence button **230**. In an embodiment, activation of the HbCO button **220** toggles the measured value displayed in the multi-mode display **206**. For example, activation of the HbCO button **220** toggles the multi-mode display **206** from displaying measured values of SpO₂ to HbCO for about ten (10) seconds. Activation of the mode/enter button **222** or the next button **224** during the ten (10) second period returns the multi-mode display **206** back to SpO₂. A skilled artisan will also recognize that activation of the HbCO button **220** may advantageously toggle through a plurality of measured values, and that such values may be displayed for short segments and then return to SpO₂, may remain displayed until further activation of the button **220**, or the like.

Activation of the mode/enter button **222** cycles through various setup menus allowing a caregiver to select or activate certain entries within the menu setup system, including alarm threshold customizations, or the like. Activation of the next button **224** can move through setup options within the menu setup system and in an embodiment is not active during normal patient monitoring. For example, a caregiver may activate the mode/enter button **222** and the next button **224** to specify high and low alarm thresholds for one or more of the measured parameters, to specify device sensitivity, trend settings, display customizations, color code parameters, or the like. In an embodiment, the high alarm setting for SpO₂ can range from about two percent (2%) to about one hundred percent (100%) with a granularity of about one percent (1%). The low alarm setting for SpO₂ can range from about one percent (1%) to about one hundred percent (100%) with a granularity of about one percent (1%). Moreover, the high

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alarm setting for pulse rate can range from about thirty (30) BPM to about two hundred and forty (240) BPM with a granularity of about five (5) BPM. The low alarm setting for pulse rate can range from about twenty five (25) BPM to about two hundred and thirty five (235) BPM with a granularity of about five (5) BPM. Other high and low ranges for other measured parameters will be apparent to one of ordinary skill in the art from the disclosure herein.

In a further embodiment, a caregiver may activate the mode/enter button **222** and the next button **224** to specify device sensitivity, such as, for example, device averaging times, probe off detection, whether to enable fast saturation calculations, or the like. Various embodiments of fast saturation calculations are disclosed in U.S. patent application Ser. No. 10/213,270, filed Aug. 5, 2002, titled "Variable Indication Estimator" and incorporated by reference herein. Using the menus, a caregiver may also advantageously enter appropriate information governing trend collection on one or more of the measured parameters, input signals, or the like.

FIG. **2** also shows the power on/off button **226**. Activation of the power on/off button **226** activates and deactivates the monitor **200**. In an embodiment, press-and-hold activation for about two (2) seconds shuts the monitor **200** off. In an additional embodiment, activation of the on/off button **226** advantageously initiates detection of a type of attached sensor. For example, activation of the on/off button **226** may advantageously cause the monitor **200** to read information from a memory on an attached sensor and determine whether sufficient wavelengths exist on the sensor to determine one or more the physiological parameters discussed in the foregoing.

An artisan will recognize from the disclosure herein that the on/off button **226** may advantageously cause an electronic determination of whether to operate in at powers consisted with the U.S. (60 Hz) or another nationality (50 Hz). In an embodiment, such automatic determination and switching is removed from the monitor **200** in order to reduce a likelihood of problematic interfering crosstalk caused by such power switching devices.

Activation of the up/down button **228** may advantageously adjust the volume of the pulse beep tone. Additionally, activation of the up/down button **228** within the menu setup system, causes the selection of values with various menu options.

Moreover, activation of the alarm silence button **230** temporarily silences audio alarms for a predetermined period, such as, for example, about one hundred and twenty (120) seconds. A second activation of the alarm silence button **230** mutes (suspends) the alarm indefinitely, while a third activation returns the monitor **200** to standard alarm monitoring. FIG. **2** also shows the alarm silence button **230** includes an alarm silenced indicator **232**. The alarm silenced indicator **232** may advantageously flash to indicate one or more alarms are temporarily silenced, may illuminate solid to indicate the alarms have been muted, or the like. Moreover, an artisan will recognize from the disclosure herein a wide variety of alarm silencing methodologies.

The monitor **200** also includes a battery level indicator **234** indicating remaining battery life. In the illustrated embodiment, four LED's indicate the status of the battery by incrementally deactivating to indicate proportionally decreasing battery life. In an embodiment, the four LED's may also change color as the battery charge decreases, and the final LED may begin to flash to indicate that the caregiver should replace the batteries.

FIG. **2** also shows the monitor **200** including an audio transducer or speaker **236**. The speaker **236** advantageously

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provides audible indications of alarm conditions, pulse tone and feedback for key-presses, or the like. Moreover, the monitor **200** includes a low signal quality indicator (“SQ” or “SIQTM”) **238**. The signal IQ indicator **238** activates to inform a caregiver that a measured value of the quality of the incoming signal is below predetermined threshold values. For example, in an embodiment, the measured value for signal IQ is at least partially based on an evaluation of the plethysmograph data’s correspondence to predetermined models or characteristics of physiological signals. In an embodiment, the signal IQ indicator **238** output may be associated with the displayed parameter. For example, the output may be associated with one threshold for the display of SpO₂ and another for the display of other parameter data.

The monitor **200** also comprises a perfusion quality index (“PITM”) bar **240** (which quantifies the measure of perfusion of the patient) where in an embodiment a plurality of LED’s activate from a bottom toward a top such that the bar “fills” to a level proportional to the measured value. In one embodiment, the PITM bar **240** shows a static value of perfusion for a given time period, such as, for example, one or more pulses. In another embodiment, or functional setting, the PITM bar **240** may advantageously pulse with a pulse rate, may hold the last reading and optionally fade until the next reading, may indicate historical readings through colors or fades, or the like. Additionally, the PITM bar **240** may advantageously change colors, flash, increasingly flash, or the like to indicate worsening measured values of perfusion.

The PITM bar **240** can be used to simply indicate inappropriate occlusion due, for example, to improper attachment of the sensor **106**. The PITM bar **240** can also be used as a diagnostic tool during low perfusion for the accurate prediction of illness severity, especially in neonates. Moreover, the rate of change in the PITM bar **240** can be indicative of blood loss, sleep arousal, sever hypertension, pain management, the presence or absence of drugs, or the like. According to one embodiment, the PITM bar **240** values may comprise a measurement of the signal strength of the arterial pulse as a percentage of the total signal received. For example, in one preferred embodiment, the alternating portion of at least one intensity signal from the sensor **106** may advantageously be divided by the static portion of the signal. For example, an infrared intensity signal may advantageously be used as it is less subjective to noise.

In an embodiment, a measurement below about 1.25% may indicate medical situations in need of caregiver attention, specifically in monitored neonates. Because of the relevance of about 1.25%, the PITM bar **240** may advantageously include level indicia **242** where the indicia **242** swap sides of the PITM bar **240**, thus highlighting any readings below about that threshold. Moreover, behavior of the PITM bar **240**, as discussed above, may advantageously draw attention to monitored values below such a threshold.

As discussed above, the monitor **200** may include output functionality that outputs, for example, trend perfusion data, such that a caregiver can monitor measured values of perfusion over time. Alternatively or additionally, the monitor **200** may display historical trace data on an appropriate display indicating the measured values of perfusion over time. In an embodiment, the trend data is uploaded to an external computing device through, for example, the multipurpose sensor connector **202** or other input output systems such as USB, serial or parallel ports or the like.

The monitor **200** also includes an alarm indicator **244** capable of providing visual queues of the status of one or more of the measured parameters. For example, the alarm indicator **244** may advantageously be green when all of the

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measured parameters are within normal conditions, may gradually fade to red, may flash, increasing flash, or the like, as one or more of the measured values approaches or passes predetermined thresholds. In an embodiment, the alarm indicator **244** activates when any parameter falls below an associated threshold, thereby advantageously informing a caregiver that perhaps a nondisplayed parameters is at an alarm condition. In another embodiment, the alarm indicator **244** may indicate the status of the parameter displayed on the multi-mode display **206**. In an embodiment, the speaker **236** may sound in conjunction with and/or in addition to the indicator **244**. Moreover, in an embodiment, an alarming parameter may automatically be displayed, may be emphasized, flashed, colored, combinations of the same or the like to draw a user’s attention to the alarming parameter.

Although the foregoing invention has been described in terms of certain preferred embodiments, other embodiments will be apparent to those of ordinary skill in the art from the disclosure herein.

FIG. 3 illustrates an exemplary display of the patient monitor **200**. As shown in FIG. 3, the display includes the multi-mode display **206**, the pulse rate display **216**, parameter indicators **208**, **210**, the HbCO bar **212** and indicator **204**, the PITM bar **240**, and the alarm indicator **244**. In an embodiment, the multi-mode display **206** and the pulse rate display **216** each comprise a plurality of seven segment displays **302** capable of displaying alpha-numeric information. As disclosed in the foregoing, the exemplary display may advantageously include color-coded parameter displays. Moreover, the exemplary display may include color progressions, flashing, flashing progressions, audible alarms, audible progressions, or the like, indicating worsening measured values of physiological data. In addition, in an embodiment, some or all of the displays may flash at a first rate to indicate attempts to acquire data when actual measured values are unavailable. Moreover, some or all of the display may flash at a second rate to indicate low signal quality where confidence is decreasing that the measured values reflect actual physiological conditions.

FIG. 4 illustrates the display of FIG. 3 showing measured values of SpO₂, BPM, perfusion, and type of sensor, according to an exemplary embodiment of the patient monitor of FIG. 1. As shown in FIG. 4, the multi-mode display **206** is displaying a percentage value of SpO₂, and the pulse rate display **216** is displaying a pulse rate in beats per minute. Accordingly, the parameter indicator **210** is activated to confirm the display of measured values of SpO₂. As disclosed in the foregoing, in an embodiment, the multi-mode display **206** is red, indicating blood oxygen measurements while the pulse rate display **216** is green, indicating normal values of a patient’s pulse.

FIG. 4 also shows the PITM bar **240** almost fully activated, representing good perfusion. In addition, the HbCO indicator **204** is showing communication with a sensor producing insufficient data to determine measured values of additional parameters, such as, HbCO. In an embodiment, such sensors may comprise sensors capable of emitting light at about two (2) different wavelengths, may comprise sensors with insufficient data stored on a memory associated therewith, or the like.

FIG. 5 illustrates the display of FIG. 3 showing measured values of HbCO, perfusion, and type of sensor, according to an exemplary embodiment of the patient monitor of FIG. 1. As shown in FIG. 5, the multi-mode display **206** is displaying a percentage value of HbCO, and the pulse rate display **216** is displaying an appropriate message indicating the HbCO measurement, such as, for example, “CO”. Also, the multi-mode display **206** has shifted the data to the left to quickly and

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efficiently indicate that the displayed parameter is other than SpO₂. Accordingly, the parameter indicator **208** is also activated to confirm the display of measured values of HbCO. As disclosed in the foregoing, in an embodiment, the multi-mode display **206** and pulse rate display message **216** are orange.

FIG. **5** also shows the PTTM bar **240** almost fully activated, representing good perfusion. In addition, the activation of the HbCO indicator **204** represents communication with a sensor capable of producing sufficient data to determine measured values of HbCO. In an embodiment, such sensors may comprise sensors capable of emitting light at about eight (8) or more different wavelengths; however, such sensors may comprise about two (2) or more different wavelengths. Moreover, such sensors may have appropriate data stored on a memory associated therewith, or the like. FIG. **5** also shows the HbCO measurement being about 20% (as illustrated on the HbCO bar **212** and multi-mode display **206**) thereby indicating a potentially dangerous situation that if exacerbated, will become quite problematic. Therefore, the alarm indicator **244** is also activated, and in some embodiments, the speaker **236** as well.

FIG. **6** illustrates the display of FIG. **3** showing measured values of SpO₂, HbCO, BPM, perfusion, and type of sensor, according to an exemplary embodiment of the patient monitor of FIG. **1**. In contrast to FIG. **4**, FIG. **6** shows that the monitor **200** is communicating with a sensor capable of producing sufficient data to determine measured values of HbCO, even though the displayed values are that of SpO₂ and BPM. Thus, FIG. **6** shows the activation of the HbCO indicator **204**, and the continuous monitoring of HbCO by the HbCO bar **212**. FIG. **6** also shows a high value of HbCO, and therefore, the indication of an alarm condition by activation of the alarm indicator **244**. In an embodiment, upon determination of an alarm condition on a nondisplayed parameter, the monitor **200** may advantageously provide an alarm indication through speaker and alarm indicator activation, automatic toggle to the nondisplayed parameter on the multi-mode display **206** for a defined or undefined time, or the like.

FIG. **7** illustrates a top elevation view of an exemplary handheld noninvasive multi-parameter patient monitor **700** capable of displaying at least HbCO and HbMet, such as, for example, the patient monitor of FIG. **1**. Patient monitors exhibiting combinations of many of the features described herein are advantageously commercially available from Masimo under the brand name "Rad 57 cm." As shown in FIG. **7**, the monitor **700** comprises a monitor similar to monitor **200** disclosed with reference to FIG. **2**. Moreover, monitor **700** further includes a multi-mode display **706** capable of displaying, for example, measurements of HbMet and BPM. In an embodiment, the display **706** has insufficient space or display real estate to display the many parameters capable of being measured by the monitor **700**. Thus, the multi-mode display **706** may advantageously cycle through two or more measured parameters. In such embodiments, the monitor **700** may also advantageously include parameter indicators **708**, **710**, providing additional visual queues as to which parameter is currently displayed. In an embodiment, the display **706** may also cycle colors, flash rates, or other audio or visual queues providing readily identifiable information as to which measured parameter is displayed. For example, when the multi-mode display **706** displays measured values of BPM that are normal, the numbers may advantageously appear in green, while normal measured values of HbMet may appear in blue. Moreover, in an embodiment, the display **706** may flash at a predefined rate when searching for saturation and at another predefined rate when a signal quality is below a predetermined threshold.

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FIG. **7** also illustrates the monitor **700** comprising user input keys **718**, including an HbCO/HbMet button **220**. In an embodiment, activation of the HbCO/HbMet button **720** toggles the measured value displayed in the multi-mode display **706**. For example, activation of the HbCO/HbMet button **720** toggles the multi-mode display **206** from displaying measured values of SpO₂ and BPM, to HbCO and HbMet for about ten (10) seconds. Activation of the mode/enter button **222** or the next button **224** during the ten (10) second period returns the multi-mode display **706** back to SpO₂ and BPM. A skilled artisan will also recognize that activation of the HbCO/HbMet button **720** may advantageously toggle through a plurality of measured values, and that such values may be displayed for short segments and then return to SpO₂ and BPM, may remain displayed until further activation of the button **720**, or the like.

The monitor **700** also comprises a coarser indication of HbMet through an HbMet bar **740**. In an embodiment, a plurality of LED's activate from a bottom toward a top such that the bar "fills" to a level proportional to the measured value, with increments at about 0.5%, about 1%, about 2%, about 3%, about 4%, about 5%, about 7.5%, about 10%, about 15% and greater than about 20%, although an artisan will recognize from the disclosure herein other useful delineations. Additionally, the HbMet bar **740** may advantageously change colors, flash, increasingly flash, or the like to indicate worsening measured values of perfusion.

Although disclosed with reference to the HbMet bar **740**, and artisan will recognize from the disclosure herein other coarse or even gross indications of HbMet, or any measured parameter. For example, a single LED may advantageously show green, yellow, and red, to indicate worsening coarse values of HbMet. Alternatively, a single LED may simply light to indicate an alarm or approaching alarm condition.

FIG. **8** illustrates an exemplary display of the patient monitor **700** of FIG. **7**. As shown in FIG. **8**, the display includes the multi-mode displays **206**, **706**, parameter indicators **208**, **210**, **708**, **710**, the HbCO bar **212** and indicator **204**, the HbMet bar **740**, and the alarm indicator **244**. In an embodiment, the multi-mode display **706** is similar to multi-mode display **206**, comprising a plurality of seven segment displays **302** capable of displaying alpha-numeric information, and capable of altering its display characteristics or aspects in a wide variety of configurations discussed with reference to the display **206**.

FIG. **9** illustrates the display of FIG. **8** showing measured values of SpO₂, BPM, HbCO, HbMet, and type of sensor according to an exemplary embodiment of the patient monitor of FIG. **1**. FIG. **9** also shows the HbMet bar **740** near the bottom and corresponding to about 1%, representing acceptable HbMet, while the HbCO bar **212** hovers at a dangerous near 20%. In addition, the HbCO indicator **204** is showing communication with a sensor producing sufficient data to determine measured values of additional parameters, such as, HbMet, HbCO or the like. In an embodiment, such sensors may comprise sensors capable of emitting light of more than two (2) different wavelengths, preferably more than four (4) different wavelengths, and more preferably eight (8) or more different wavelengths.

FIG. **10** illustrates the display of FIG. **8** showing measured values of HbCO, HbMet, and type of sensor according to an exemplary embodiment of the patient monitor of FIG. **1**. As shown in FIG. **10**, the multi-mode display **706** is displaying a percentage value of HbMet that is shifted using the parameter indicator **708**. The data has been advantageously shifted to the left to quickly and efficiently indicate that the displayed parameter is other than BPM. Accordingly, the parameter indicator **708** is also activated to confirm the display of mea-

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sured values of HbMet. As disclosed in the foregoing, in an embodiment, the multi-mode display **706** is blue.

FIG. **10** also shows the HbMet bar **740** nearly empty, representing acceptable HbMet. In addition, the activation of the HbCO indicator **204** represents communication with a sensor capable of producing sufficient data to determine measured values of HbCO. In an embodiment, such sensors may have appropriate data stored on a memory associated therewith, or the like. FIG. **10** also shows the HbCO measurement being about 20% (as illustrated on the HbCO bar **212** and multi-mode display **206**) thereby indicating a potentially dangerous situation that if exacerbated, will become quite problematic. Therefore, the alarm indicator **244** is also activated, and in some embodiments, the speaker **236** as well.

FIG. **11A** illustrates a perspective view of an exemplary noninvasive multi-parameter patient monitor **1100**, such as, for example, the patient monitor of FIG. **1**. Moreover, FIGS. **11B-11E** illustrate exemplary display screens of the patient monitor of FIG. **11A**. As shown in FIGS. **11A-11B**, an embodiment of the monitor **1100** includes a display **1101** showing a plurality of parameter data. For example, the display may advantageously comprise a CRT or an LCD display including circuitry similar to that available on oximeters commercially available from Masimo Corporation of Irvine, Calif. sold under the name Radical™, and disclosed in the U.S. patents referenced above and incorporated above. However, an artisan will recognize from the disclosure herein many commercially available display components capable of displaying multiple parameter data along with the ability to display graphical data such as plethysmographs, trend traces, and the like.

In an embodiment, the display includes a measured value of SpO₂ **1102**, a measured value of pulse rate **1104** in BPM, a plethysmograph **1106**, a measured value of HbCO **1108**, a measured value of HbMet **1110**, a measured value of a perfusion quality **1112**, a measured value of Hbt **1114**, and a derived value of fractional saturation "SpaO₂" **1116**. In an embodiment, SpaO₂ comprises HbO₂ expressed as a percentage of the four main hemoglobin species, i.e., HbO₂, Hb, HbCO, and HbMet.

In an embodiment, one or more of the foregoing parameter includes trending or prediction indicators **1118** showing the current trend or prediction for that corresponding parameter. In an embodiment, the indicators **1118** may advantageously comprise an up arrow, a down arrow, and a hyphen bar to indicate up trending/prediction, down trending/prediction, or neutral trending/prediction.

FIG. **11C** illustrates an exemplary display screen showing trend graph **1140** including trend line **1142** for HbMet. In an embodiment, the trend line **1142** may be advantageously colored for quick straightforward recognition of the trending parameter, may be associated with any one or more of the foregoing alarm attributes, may include trending lines for other parameters, or the like. The display screen also shows trending directional indicators **1142**, **1144** for many of the displayed physiological parameters. In an embodiment, the directional indicators **1142**, **1144** may advantageously comprises arrows showing the recent trend, predicted trend, user-customizable trend, combinations thereof, or the like for the associated parameters. In an embodiment, the directional indicators **1142**, **1144** comprises an up arrow indicating a rising trend/predicted trend, a middle bar indicating a somewhat stable trend/predicted trend, and a down arrow indicating a lowering trend/predicted trend. An artisan will recognize a wide variety of other directional indicators **1142**, **1144** from the disclosure herein.

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FIG. **11D** shows an exemplary display screen in vertical format. Such vertical format could be user actuated or based on a gravity switch. FIGS. **11E-11F** illustrate additional displays of various physiological parameters similar to those discussed in the foregoing. As shown in FIG. **11G**, the display includes a measured value of SpO₂ **1162**, a measured value of pulse rate **1164** in BPM, a plethysmograph **1166**, a HbCO bar **1168**, and a HbMet bar **1170**. In an embodiment, the HbCO bar **1168** and HbMet bar **1170** may advantageously behave the same or similarly to the HbCO bar **212** and HbMet bar **712**. Moreover, similar bars may advantageously display any of the physiological parameters discussed herein using display indicia appropriate to that parameter. For example, a SpO₂ or SpaO₂ bar may advantageously range from about 0% to about 100%, and more preferably range from about 50% to about 100%, while a Hbt bar may advantageously range from about 0 to about 30.

Moreover, similar to the disclosure above, the measured value of SpO₂ **1162** may advantageously toggle to measured values of HbCO, HbMet, Hbt, or the like based on, for example, actuation of user input keys, or the like.

In addition to the foregoing, the display may also include graphical data showing one or more color-coded or other identifying indicia for traces of trend data. Moreover, other graphical presentations may advantageously provide readily identifiable indications of monitored parameters or combinations of monitored parameters of the patient. For example, in an embodiment, the display includes a SpaO₂ graph **1172**. The SpaO₂ graph **1172** plots SpO₂ as a function of other blood analytes (1-SpaO₂), where SpaO₂ comprises HbO₂ expressed as a percentage of the four main hemoglobin species, i.e., HbO₂, Hb, HbCO, and HbMet. Thus, as shown in FIG. **11C**, as the slope of the displayed line or arrow increases, the caregiver can readily note that the majority of hemoglobin carriers are being used to carry oxygen, and not, for example, harmful carbon monoxide. On the other hand, as the slope decreases, the caregiver can readily and advantageously note that the number of hemoglobin species available to carry oxygen is decreasing, regardless of the current value of SpO₂. Moreover, the length of the arrow or line also provides an indication of wellness, e.g., the higher the line the more oxygen saturation, the lower the line, the more likely there may be desaturation event, or the like.

Thus, the SpaO₂ graph **1172** provides the caregiver with the ability to recognize that even though the measured value of SpO₂ may be within acceptable ranges, there are potentially an unacceptable number of hemoglobin carriers unavailable for carrying oxygen, and that other potential problems may exist, such as, for example, harmful carbon monoxide levels, or the like. In an embodiment, various alarm conditions may cause the graph **1172** to change color, flash, or any combination of alarm indications discussed in the foregoing. Moreover, FIG. **11** illustrates yet an additional display of the foregoing parameters.

An embodiment may also include the monitor **1000** advantageously defining regions of wellness/severity of the monitored patient. For example, because the graph **1172** comprises two dimensions, the monitor **1000** may advantageously define regions where the patient's measured physiological parameters are considered acceptable, regions where the patient is considered at risk, regions where the patient is critical, and the like. For example, one region of acceptability may include a high SpO₂ and a low 1-SpaO₂, another region of risk may include a high SpO₂ and a high 1-SpaO₂, and another critical region may include a low SpO₂ and a high 1-SpaO₂. Moreover, an artisan will recognize from the dis-

closure herein that different parameters may also be combined to provide readily identifiable indications of patient wellness.

In addition to or as an alternative to the two dimensional SpO₂ graph **1172**, the monitor **1000** may also include a three dimensional graph, such as, for example, extending the graph **1172** along the variable of time. In this embodiment, the forgoing regions advantageously become three dimensional surfaces of wellness. Moreover, trend data may also be advantageously added to the surface to provide a history of when particular monitored parameters dipped in and out of various surfaces of wellness, risk, criticality, or the like. Such trend data could be color-coded, text identified, or the like. An artisan will also recognize that such surfaces may be dynamic. For example, measurements of HbCO > about 5 may dictate that trend data showing SpO₂ < about 90% should be considered critical; however, measurements of HbCO < about 5 may dictate only SpO₂ < about 85% would be critical. Again, an artisan will recognize from the disclosure herein other parameter combinations to create a wide variety of wellness/critical regions or surfaces that provide readily available visual or audio indications of patient well being, trigger specific alarms, or the like.

Moreover, the monitor **1000** may advantageously employ enlargement or reorganization of parameter data based on, for example, the severity of the measurement. For example, the monitor **1000** may display values for HbCO in a small portion of the screen or in the background, and when HbCO begins to approach abnormal levels, the small portion may advantageously grown as severity increases, even in some embodiments to dominate the display. Such visual alarming can be combined with audio alarms such as announcements, alarms, rising frequencies, or the like, and other visual alarms such as flashing, coloration, or the like to assist a caregiver in noticing the increasing severity of a monitored parameter. In an embodiment, a location of the display of an alarming value is changed to be displayed in a larger display area, such as **1102**, so as to be readily noticeable and its display values readily ascertainable.

Although the foregoing invention has been described in terms of certain preferred embodiments, other embodiments will be apparent to those of ordinary skill in the art from the disclosure herein. For example, the monitor **100** may advantageously be adapted to monitor or be included in a monitor capable of measuring physiological parameters other than those determined through absorption spectroscopy, such as, for example, blood pressure, ECG, EKG, respiratory rates, volumes, inputs for blood pressure sensors, acoustical sensors, and the like. Moreover, the monitor **100** may be adapted for wireless communication to and from the sensor **106**, and/or to and from other monitoring devices, such as, for example, multi-parameter or legacy monitoring devices.

Also, other combinations, omissions, substitutions and modifications will be apparent to the skilled artisan in view of the disclosure herein. Accordingly, the present invention is not intended to be limited by the reaction of the preferred embodiments, but is to be defined by reference to the appended claims.

Additionally, all publications, patents, and patent applications mentioned in this specification are herein incorporated by reference to the same extent as if each individual publication, patent, or patent application was specifically and individually indicated to be incorporated by reference.

What is claimed is:

1. A patient monitor capable of measuring at least two physiological parameters, the patient monitor comprising a display capable of displaying a measured value of a first

physiological parameter of body tissue of a monitored patient in a first display area or displaying a measured value of a second physiological parameter of the body tissue in a second display area where the first display area and the second display area comprise at least some common display area capable of displaying information, wherein the common display area changes from displaying one of the measured values of the first or second physiological parameter to displaying the other of the measured values based on an occurrence of an event, the event being the measured value of one of the first or second physiological parameters approaching one or more threshold values indicative of a worsening state of a patient.

2. The patient monitor of claim 1, wherein the first display area and the second display area comprise the common display area.

3. The patient monitor of claim 1, wherein activation of a user input causes the common display area to change from displaying one of the measured value of the first or second physiological parameter to displaying the other of the measured value of the first or second physiological parameter.

4. The patient monitor of claim 1, wherein the common display area is configured to default to displaying one of the measured values of the first or second physiological parameters.

5. The patient monitor of claim 1, wherein the measured value of the first physiological parameter comprises an invasively measured value.

6. The patient monitor of claim 1, wherein the measured value of the first physiological parameter comprises a non-invasively measured value.

7. The patient monitor of claim 1, wherein the measured value of the first physiological parameter comprises glucose.

8. The patient monitor of claim 1, wherein the measured value of the first physiological parameter comprises an indication of oxygen saturation and the measured value of the second physiological parameter comprises an indication of carbon monoxide saturation.

9. The patient monitor of claim 1, wherein the measured value of the first physiological parameter comprises an indication of oxygen saturation and the measured value of the second physiological parameter comprises an indication of methemoglobin saturation.

10. The patient monitor of claim 1, wherein the measured value of the first physiological parameter comprises an indication of carbon monoxide saturation and the measured value of the second physiological parameter comprises an indication of methemoglobin saturation.

11. The patient monitor of claim 1, wherein an aspect of the display changes to illustrate a change in the severity of one of the measured values of the first or second physiological parameters.

12. The patient monitor of claim 11, wherein the aspect that changes comprises a display color.

13. The patient monitor of claim 11, wherein the aspect that changes comprises a display size.

14. The patient monitor of claim 11, wherein the aspect that changes comprises a display intensity.

15. A patient monitor capable of measuring at least two physiological parameters, the patient monitor comprising a display capable of displaying a measured value of a first physiological parameter of body tissue of a monitored patient in a first display area or displaying a measured value of a second physiological parameter of the body tissue in a second display area where the first display area and the second display area comprise at least some common display area capable of displaying information, wherein the common display area changes from displaying one of the measured values

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of the first or second physiological parameters to displaying the other of the measured values of the first or second physiological parameters based on an occurrence of an event, the event being one of the measured values of the first or second physiological parameters alarming.

16. The patient monitor of claim 15, wherein an aspect of an alarm changes when the common display area changes from displaying one of the measured values of the first or second physiological parameters.

17. The patient monitor of claim 16, wherein the aspect that changes comprises a display color.

18. A patient monitor capable of measuring at least two physiological parameters, the patient monitor comprising a display capable of displaying a measured value of a first physiological parameter of body tissue of a monitored patient in a first display area or displaying a measured value of a second physiological parameter of the body tissue in a second display area where the first display area and the second display area comprise at least some common display area capable of displaying information, wherein the common display area changes from displaying one of the measured values of the first or second physiological parameters to displaying the other of the measured values of the first or second physiological parameters automatically based on which is a more critical one of the measured values of the first or second physiological parameters.

19. The patient monitor of claim 18, wherein measured values of the first and second physiological parameters are determined using an output signal of a light sensitive detector capable of detecting light attenuated by the body tissue.

20. The patient monitor of claim 18, wherein at least one of measured physiological parameters is determined noninvasively.

21. A method of displaying two physiological parameter measurements using a display location of a display of a patient monitoring device, the display location being generally capable of displaying a single physiological parameter measurement, the method comprising:

displaying a measured value of a first physiological parameter in a display location of an electronic display; and replacing the display of the measured value of the first physiological parameter with a display of a measured value of a second physiological parameter in the display location when a change in the measurement of the second physiological parameter indicates a worsening state of the patient.

22. The method of claim 21, wherein the indication of the worsening state comprises an alarm condition.

23. The method of claim 21, wherein the measured value of the first physiological parameter comprises an invasively measured value.

24. The method of claim 21, wherein the measured value of the first physiological parameter comprises an indication of oxygen saturation and the measured value of the second physiological parameter comprises an indication of carbon monoxide saturation.

25. The method of claim 21, wherein the measured value of the first physiological parameter comprises an indication of oxygen saturation and the measured value of the second physiological parameter comprises an indication of methemoglobin saturation.

26. The method of claim 21, wherein the measured value of the first physiological parameter comprises an indication of carbon monoxide saturation and the measured value of the second physiological parameter comprises an indication of methemoglobin saturation.

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27. A patient monitor capable of determining a plurality of physiological parameters from an output signal of a light sensitive detector capable of detecting light attenuated by body tissue, the patient monitor comprising:

a display capable of displaying a measured value of a first blood parameter of body tissue of a monitored patient or displaying a measured value of a second blood parameter of the body tissue; and

a user input button, the activation of which causes the display to change from displaying the measured value of the first blood parameter to displaying the measured value of the second blood parameter, wherein the display also changes from displaying the measured value of the first blood parameter to displaying the measured value of the second blood parameter when the second blood parameter passes an alarm threshold,

wherein the measured values of the first and second blood parameters are determined using an output signal of a noninvasive light sensitive detector capable of detecting light attenuated by the body tissue.

28. The patient monitor of claim 27, wherein the display shifts a positioning of the display of the second blood parameter with respect to a positioning of the display of the first blood parameter.

29. The patient monitor of claim 27, wherein the change is for a predetermined duration and after expiration of the predetermined duration, the display changes back to displaying the measured value of the first blood parameter.

30. The patient monitor of claim 27, wherein the display of the measured value of the first blood parameter comprises a first color under normal conditions and the display of the measured value of the second blood parameter comprises a second color under normal conditions.

31. The patient monitor of claim 27, further comprising a sensor indicator capable of indicating whether an attached sensor can provide sufficient data to determine the measured value of the second blood parameter.

32. The patient monitor of claim 27, wherein the attached sensor can provide data through the output signal and through a memory device.

33. The patient monitor of claim 27, wherein the display displays the first blood parameter when the attached sensor cannot provide the sufficient data.

34. The patient monitor of claim 27, further comprising a memory for storing trend data on one or more of the first and second blood parameters.

35. The patient monitor of claim 27, further comprising an indicator capable of indicating the signal quality of the signals used to determine at least one of the measured values of the first and second blood parameters.

36. The patient monitor of claim 27, further comprising an alarm corresponding to either of the measured values of the first and second blood parameters falling below predetermined associated threshold values.

37. The patient monitor of claim 36, wherein the alarm comprises at least one of an audio or visual alarm.

38. The patient monitor of claim 27, further comprising an additional display indicating perfusion through the body tissue.

39. The patient monitor of claim 27, wherein the first blood parameter comprises a percent oxygen saturation and the second blood parameter comprises a percent carbon monoxide saturation.

40. The patient monitor of claim 39, comprising an additional display capable of indicating the percent carbon monoxide saturation.

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41. The patient monitor of claim 39, comprising an additional display capable of indicating the percent methemoglobin saturation.

42. The patient monitor of claim 27, wherein the display comprises a first display and the patient monitor further comprises a second display capable of displaying a pulse rate. 5

43. The patient monitor of claim 42, wherein the second display is capable of displaying the pulse rate when the first display displays the measured value of the first blood parameter.

44. The patient monitor of claim 42, wherein the second display is capable of displaying indicia identifying the second blood parameter when the first display displays the measured value of the second blood parameter.

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45. The patient monitor of claim 27, wherein a first activation type of the user input button causes the change to be for a predetermined duration and wherein a second activation type causes the change to be for an undetermined duration.

46. The patient monitor of claim 45, wherein the first activation type comprises a first depression of the user input button and the second activation type comprises an additional depression of the user input button.

47. The patient monitor of claim 45, wherein the first activation type comprises a short duration first depression of the user input button and the second activation type comprises a long duration first depression of the user input button. 10

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 8,190,223 B2
APPLICATION NO. : 11/367033
DATED : May 29, 2012
INVENTOR(S) : Ammar Al-Ali et al.

Page 1 of 1

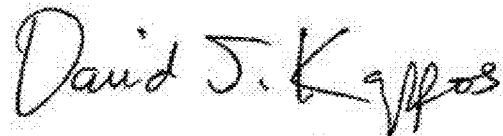
It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

On Title Page 2 (Item 56), Column 1, Line 15 (Approx.), Under U.S. Patent Documents,
below "Martin" insert --4,854,328 |08-1989 |Pollack--.

On Title Page 4 (Item 56), Column 1, Line 75, Under U.S. Patent Documents, change "Chin et
al." to --O'Neil et al.--.

In Column 18, Line 54, change "11" to --11H--.

Signed and Sealed this
Thirteenth Day of November, 2012

A handwritten signature in black ink that reads "David J. Kappos". The signature is written in a cursive, flowing style with a large initial "D".

David J. Kappos
Director of the United States Patent and Trademark Office

(12) **EX PARTE REEXAMINATION CERTIFICATE** (9610th)
United States Patent
Al-Ali et al.

(10) **Number:** **US 8,190,223 C1**
(45) **Certificate Issued:** **Apr. 24, 2013**

(54) **NONINVASIVE MULTI-PARAMETER PATIENT MONITOR**

(75) Inventors: **Ammar Al-Ali**, Tustin, CA (US); **Joe Kiani**, Laguna Niguel, CA (US); **Mohamed Diab**, Mission Viejo, CA (US); **Greg Olsen**, Irvine, CA (US); **Roger Wu**, Irvine, CA (US); **Rick Fishel**, Orange, CA (US)

(73) Assignee: **Cercacor Laboratories, Inc.**, Irvine, CA (US)

Reexamination Request:

No. 90/012,559, Sep. 13, 2012

Reexamination Certificate for:

Patent No.: **8,190,223**
Issued: **May 29, 2012**
Appl. No.: **11/367,033**
Filed: **Mar. 1, 2006**

Certificate of Correction issued Nov. 13, 2012

Related U.S. Application Data

(60) Provisional application No. 60/657,596, filed on Mar. 1, 2005, provisional application No. 60/657,281, filed on Mar. 1, 2005, provisional application No. 60/657,268, filed on Mar. 1, 2005, provisional application No. 60/657,759, filed on Mar. 1, 2005.

(51) **Int. Cl.**
A61B 5/00 (2006.01)

(52) **U.S. Cl.**
USPC **600/300; 600/323; 600/324**

(58) **Field of Classification Search** None
See application file for complete search history.

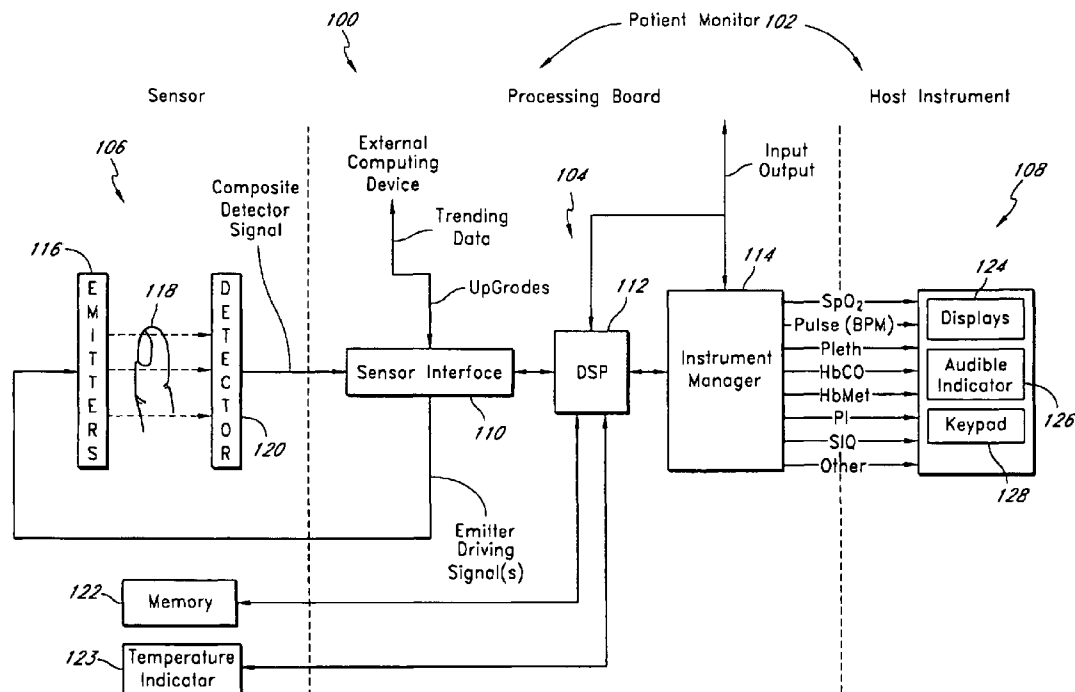
(56) **References Cited**

To view the complete listing of prior art documents cited during the proceeding for Reexamination Control Number 90/012,559, please refer to the USPTO's public Patent Application Information Retrieval (PAIR) system under the Display References tab.

Primary Examiner — Robert Nasser

(57) **ABSTRACT**

Embodiments of the present disclosure include a handheld multi-parameter patient monitor capable of determining multiple physiological parameters from the output of a light sensitive detector capable of detecting light attenuated by body tissue. For example, in an embodiment, the monitor is capable of advantageously and accurately displaying one or more of pulse rate, plethysmograph data, perfusion quality, signal confidence, and values of blood constituents in body tissue, including for example, arterial carbon monoxide saturation ("HbCO"), methemoglobin saturation ("HbMet"), total hemoglobin ("Hbt"), arterial oxygen saturation ("SpO₂"), fractional arterial oxygen saturation ("SpaO₂"), or the like. In an embodiment, the monitor advantageously includes a plurality of display modes enabling more parameter data to be displayed than the available physical display real estate.



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EX PARTE
REEXAMINATION CERTIFICATE
ISSUED UNDER 35 U.S.C. 307

THE PATENT IS HEREBY AMENDED AS
INDICATED BELOW.

Matter enclosed in heavy brackets [] appeared in the patent, but has been deleted and is no longer a part of the patent; matter printed in italics indicates additions made to the patent.

AS A RESULT OF REEXAMINATION, IT HAS BEEN DETERMINED THAT:

The patentability of claims 21-26 is confirmed.

Claims 1, 3, 7, 13, 15, 18, 27-28 and 45 are determined to be patentable as amended.

Claims 2, 4-6, 8-12, 14, 16-17, 19-20, 29-44 and 46-47, dependent on an amended claim, are determined to be patentable.

1. A patient monitor capable of measuring at least two physiological parameters, the patient monitor comprising a display capable of displaying a measured value of a first physiological parameter of body tissue of a monitored patient in a first display area or displaying a measured value of a second physiological parameter of the body tissue in a second display area where the first display area and the second display area comprise at least some common display area capable of displaying information, wherein *in* the common display area [changes from displaying], *the display of* one of the measured values of the first or second physiological parameter [to displaying] *is replaced with* the other of the measured values based on an occurrence of an event, the event being the measured value of one of the first or second physiological parameters approaching one or more threshold values indicative of a worsening state of a patient.

3. The patient monitor of claim 1, wherein activation of a user input causes the common display area to [change from displaying] *replace* one of the measured value of the first or second physiological parameter [to displaying] *with* the other of the measured value of the first or second physiological parameter.

7. [The patient monitor of claim 1] *A patient monitor capable of measuring at least two physiological parameters, the patient monitor comprising a display capable of displaying a measured value of a first physiological parameter of body tissue of a monitored patient in a first display area or displaying a measured value of a second physiological parameter of the body tissue in a second display area where the first display area and the second display area comprise at least some common display area capable of displaying information, wherein the common display area changes from displaying one of the measured values of the first or second physiological parameter to displaying the other of the measured values based on an occurrence of an event, the event being the measured value of one of the first or second physiological parameters approaching one or more threshold values indicative of a worsening state of a patient, wherein the measured value of the first physiological parameter comprises glucose.*

13. [The patient monitor of claim 11] *A patient monitor capable of measuring at least two physiological parameters, the patient monitor comprising a display capable of displaying a measured value of a first physiological parameter of*

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body tissue of a monitored patient in a first display area or displaying a measured value of a second physiological parameter of the body tissue in a second display area where the first display area and the second display area comprise at least some common display area capable of displaying information, wherein the common display area changes from displaying one of the measured values of the first or second physiological parameter to displaying the other of the measured values based on an occurrence of an event, the event being the measured value of one of the first or second physiological parameters approaching one or more threshold values indicative of a worsening state of a patient, wherein an aspect of the display changes to illustrate a change in the severity of one of the measured values of the first or second physiological parameters, wherein the aspect that changes comprises a display size.

15. A patient monitor capable of measuring at least two physiological parameters, the patient monitor comprising a display capable of displaying a measured value of a first physiological parameter of body tissue of a monitored patient in a first display area or displaying a measured value of a second physiological parameter of the body tissue in a second display area where the first display area and the second display area comprise at least some common display area capable of displaying information, wherein *in* the common display area [changes from displaying], *the display of* one of the measured values of the first or second physiological parameters [to displaying] *is replaced with* the other of the measured values of the first or second physiological parameters based on an occurrence of an event, the event being one of the measured values of the first or second physiological parameters alarming.

18. A patient monitor capable of measuring at least two physiological parameters, the patient monitor comprising a display capable of displaying a measured value of a first physiological parameter of body tissue of a monitored patient in a first display area or displaying a measured value of a second physiological parameter of the body tissue in a second display area where the first display area and the second display area comprise at least some common display area capable of displaying information, wherein *in* the common display area [changes from displaying], *the display of* one of the measured values of the first or second physiological parameters [to displaying] *is replaced with* the other of the measured values of the first or second physiological parameters automatically based on which is a more critical one of the measured values of the first or second physiological parameters.

27. A patient monitor capable of determining a plurality of physiological parameters from an output signal of a light sensitive detector capable of detecting light attenuated by body tissue, the patient monitor comprising:

a display capable of displaying a measured value of a first blood parameter of body tissue of a monitored patient or displaying a measured value of a second blood parameter of the body tissue; and

a user input button, the activation of which [causes] *replaces* the display [to change from displaying] *of* the measured value of the first blood parameter [to displaying] *with* the measured value of the second blood parameter, wherein the display [also changes from displaying] *of* the measured value of the first blood parameter [to displaying] *is replaced by* the measured value of the second blood parameter when the second blood parameter passes an alarm threshold,

wherein the measured values of the first and second blood parameters are determined using an output signal of a

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noninvasive light sensitive detector capable of detecting light attenuated by the body tissue.

28. [The patient monitor of claim 27] *A patient monitor capable of determining a plurality of physiological parameters from an output signal of a light sensitive detector capable of detecting light attenuated by body tissue, the patient monitor comprising:*

a display capable of displaying a measured value of a first blood parameter of body tissue of a monitored patient or displaying a measured value of a second blood parameter of the body tissue; and

a user input button, the activation of which causes the display to change from displaying the measured value of the first blood parameter to displaying the measured value of the second blood parameter, wherein the display also changes from displaying the measured value of the first blood parameter to displaying the measured value of the second blood parameter when the second blood parameter passes an alarm threshold,

wherein the measured values of the first and second blood parameters are determined using an output signal of a noninvasive light sensitive detector capable of detecting light attenuated by the body tissue,

wherein the display shifts a positioning of the display of the second blood parameter with respect to a positioning of the display of the first blood parameter.

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45. [The patient monitor of claim 27] *A patient monitor capable of determining a plurality of physiological parameters from an output signal of a light sensitive detector capable of detecting light attenuated by body tissue, the patient monitor comprising:*

a display capable of displaying a measured value of a first blood parameter of body tissue of a monitored patient or displaying a measured value of a second blood parameter of the body tissue; and

a user input button, the activation of which causes the display to change from displaying the measured value of the first blood parameter to displaying the measured value of the second blood parameter, wherein the display also changes from displaying the measured value of the first blood parameter to displaying the measured value of the second blood parameter when the second blood parameter passes an alarm threshold,

wherein the measured values of the first and second blood parameters are determined using an output signal of a noninvasive light sensitive detector capable of detecting light attenuated by the body tissue,

wherein a first activation type of the user input button causes the change to be for a predetermined duration and wherein a second activation type causes the change to be for an undetermined duration.

* * * * *

EXHIBIT 2



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
90/012,559	09/13/2012	8190223	403381US104RX	6710

20995	7590	10/23/2012
KNOBBE MARTENS OLSON & BEAR LLP		
2040 MAIN STREET		
FOURTEENTH FLOOR		
IRVINE, CA 92614		

EXAMINER	
NASSER, ROBERT L	

ART UNIT	PAPER NUMBER
3992	

MAIL DATE	DELIVERY MODE
10/23/2012	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.



UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patents and Trademark Office
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Alexandria, VA 22313-1450
www.uspto.gov

THIRD PARTY REQUESTER'S CORRESPONDENCE ADDRESS
OBLON, SPIVAK, MCCLELLAND MAIER &
NEUSTADT, L.L.P.
1940 DUKE STREET
ALEXANDRIA, VA. 22314

Date:

EX PARTE REEXAMINATION COMMUNICATION TRANSMITTAL FORM

REEXAMINATION CONTROL NO. : 90012559
PATENT NO. : 8190223
ART UNIT : 3993

Enclosed is a copy of the latest communication from the United States Patent and Trademark Office in the above identified ex parte reexamination proceeding (37 CFR 1.550(f)).

Where this copy is supplied after the reply by requester, 37 CFR 1.535, or the time for filing a reply has passed, no submission on behalf of the ex parte reexamination requester will be acknowledged or considered (37 CFR 1.550(g)).

Order Granting / Denying Request For Ex Parte Reexamination	Control No.	Patent Under Reexamination
	90/012,559	8190223
	Examiner	Art Unit
	ROBERT NASSER	3992

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

The request for *ex parte* reexamination filed 13 September 2012 has been considered and a determination has been made. An identification of the claims, the references relied upon, and the rationale supporting the determination are attached.

Attachments: a) ☐ PTO-892, b) ☒ PTO/SB/08, c) ☐ Other: _____

1. ☒ The request for *ex parte* reexamination is GRANTED.

RESPONSE TIMES ARE SET AS FOLLOWS:

For Patent Owner's Statement (Optional): TWO MONTHS from the mailing date of this communication (37 CFR 1.530 (b)). **EXTENSIONS OF TIME ARE GOVERNED BY 37 CFR 1.550(c).**

For Requester's Reply (optional): TWO MONTHS from the **date of service** of any timely filed Patent Owner's Statement (37 CFR 1.535). **NO EXTENSION OF THIS TIME PERIOD IS PERMITTED.** If Patent Owner does not file a timely statement under 37 CFR 1.530(b), then no reply by requester is permitted.

2. ☐ The request for *ex parte* reexamination is DENIED.

This decision is not appealable (35 U.S.C. 303(c)). Requester may seek review by petition to the Commissioner under 37 CFR 1.181 within ONE MONTH from the mailing date of this communication (37 CFR 1.515(c)). **EXTENSION OF TIME TO FILE SUCH A PETITION UNDER 37 CFR 1.181 ARE AVAILABLE ONLY BY PETITION TO SUSPEND OR WAIVE THE REGULATIONS UNDER 37 CFR 1.183.**

In due course, a refund under 37 CFR 1.26 (c) will be made to requester:

- a) ☐ by Treasury check or,
b) ☐ by credit to Deposit Account No. _____, or
c) ☐ by credit to a credit card account, unless otherwise notified (35 U.S.C. 303(c)).

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cc:Requester (if third party requester)

Application/Control Number: 90/012,559
Art Unit: 3992

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Decision on Request

A substantial new question of patentability affecting claims 1-47 of US Patent 8,190,223 to Al-Ali et al (the '223 patent) is deemed to have been raised by the request for Ex Parte Reexamination, filed 9/13/2012.

Prior Art Cited in the Request

U.S. Patent Application Publication 2002/0082488, filed December 21, 2001 and published June 27, 2002 to Al-Ali et al. ("A1-Ali").

U.S. Patent No. 6,658,276, filed February 12, 2002 and issued December 2, 2003 to Kiani et al. ("Kiani").

U.S. Patent No. 5,842,979, filed February 14, 1997 and issued December 1, 1998 to Jarman ("Jarman").

U.S. Patent No. 4,051,522, filed May 5, 1975 and issued September 27, 1977 to Healy et al. ("Healy").

U.S. Patent Application Publication 2003/0120164, filed December 20, 2001 and published June 26, 2003 to Nielsen ("Nielsen").

U.S. Patent No. 5,743,262, filed June 7, 1995 and issued April 28, 1998 to Lepper et al. ("Lepper").

Issues Raised By the Request

Issue 1: The request alleges that the technological teachings of Al-Ali et al alone or in combination with other references raise a substantial new question (SNQ) of patentability regarding claims 1-47 of the '223 patent as follows:

Application/Control Number: 90/012,559
Art Unit: 3992

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A. The request alleges that the technological teachings of Al-Ali raise a substantial new question of patentability with respect to claims 1-4, 6, 15, 18-22, 27, 28, 36, 42, and 43.

B. The request alleges that the technological teachings of Al-Ali and Kianl raise a substantial new question of patentability with respect to claims 29, 31-35, 37, 38, and 44-47

C. The request alleges that the technological teachings of Al-Ali and Jarman raise a substantial new question of patentability with respect to claims 8-10, 24-26, and 39-41.

D. The request alleges that the technological teachings of Al-Ali and Healy raise a substantial new question of patentability with respect to claims 11-14, 16, 17, and 30

E. The request alleges that the technological teachings of Al-Ali and Nielsen raise a substantial new question of patentability with respect to claims 5 and 23.

F. The request alleges that the technological teachings of Al-Ali and Lepper raise a substantial new question of patentability with respect to claim 7.

Al-Ali published June 27, 2002, which predates the '223 patent by more than one year. Kianl issued December 2, 2003, which predates the '223 patent by more than one year. Jarman issued December 1, 1998, which predates the '223 patent by more than one year. Healy issued September 27, 1997 which predates the '223 patent by more than one year. Nielsen published December 20, 2001, which predates the '223

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Art Unit: 3992

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patent by more than one year. Lepper issued April 28, 1998, which predates the '223 patent by more than one year. As such, Al-Ali, Kianl, Jarman, Healy, Nielsen, and Lepper all qualify as prior art under 35 USC 102(b).

Background

Claims 1-47 are the current claims in US patent 8,190,223 to Al-Ali et al, which issued May 29, 2012 from application 11/367,033, filed March 1, 2006. The '223 application claims priority to US provisional applications 60/657596, 60/657281, 60/657268, and 60/657759, all filed March 1, 2005.

The '188 patent is generally drawn to pulse oximeter with a backup alarm that is activated when a first alarm is determined to be unavailable.

Prosecution of the '033 application resulted in issuance of claims 1-3, 7, 9-13, 15-29, and 41-63 (patent claims 1-47). The examiner did not issue a reasons for allowance. However, after the first action in which all of the pending claims were rejected, the applicant submitted an amendment on September 15, 2012, in which claim 1 was amended to recite that the common area of the displaying changes from displaying one of the parameters to the other when one of the parameters approaches one or more threshold values indicating a worsening of a patient's condition. Claim 7 (patent claim 15) was amended to recite that the common area of the displaying changes from displaying one of the parameters to the other when one of the parameters alarms. Claim 10 (patent claim 18) was amended to recite that the common area of the

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displaying changes from displaying one of the parameters to the other based on which is a more critical value of the measured values of the parameters. Claim 24 (patent claim 21) was amended to recite that the display replaces the displayed first parameter with a second parameter when the value of the second parameter indicates a worsening of a patient's condition. Claim 43 (patent claim 27) was amended to recite that the display changes from displaying a first blood parameter to displaying a second blood parameter when the second parameter exceeds an alarm limit. In an interview summary of an August 17, 2011 interview, the examiner Nielsen did not change the output based on an alarm threshold or an evaluation of the relative criticality of the parameters. No further comment distinguishing the claims from the references was made.

As such, it appears from the record that the key feature missing at the time of allowance of claims 1-3, 7, 9-13, 15-29, and 41-63 of the '223 patent was a the display changing from displaying one of a first and second parameters to displaying the other of the first and second parameters, when a measured value of one of the parameters indicates that the patient's condition is worsening (claims 1 and 21), when one of the parameters is in an alarm state (claims 15 and 27), or based on the relative criticality of the two parameters (claim 18).

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Scope of Reexamination

On November 2, 2002, Public Law 107-273 was enacted. Title III, Subtitle A, Section 13105, part (a) of the Act revised the reexamination statute by adding the following new last sentence to 35 U.S.C. 303(a) and 312(a):

The existence of a substantial new question of patentability is not precluded by the fact that a patent or printed publication was previously cited by or to the Office or considered by the Office.

For any reexamination ordered on or after November 2, 2002, the effective date of the statutory revision, reliance on previously cited/considered art, i.e., "old art," does not necessarily preclude the existence of a substantial new question of patentability (SNQ) that is based exclusively on that old art. Rather, determinations on whether a SNQ exists in such an instance shall be based upon a fact-specific inquiry done on a case-by-case basis. In the present instance, an SNQ appears to exist based on the existence of newly uncovered prior art that was not before the examiner at the time of examination.

Analysis

Issue 1: Healy is new art. Al-Ali was of record during prosecution of the '233 patent, but was never applied or commented on. Kianl, Jarman, Nielsen, and Lepper were applied during prosecution of the '233 patent, but were not used in combination with Al-Ali. As such, the references are being viewed in a new light.

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It is agreed that the technological teachings of Al-Ali raise substantial new question of patentability with respect to claims 1-47 of the '233 patent. Al-Ali teaches a multi-parameter, multi-site display of two blood parameters, SPaO₂ and SPvO₂, at two tissue sites. Each display parameter has its own display area as well as a common display area 1660 where the waveforms are displayed (see figures 16a and 16b). Upon occurrence of a triggering event, such as an alarm condition, the display switches from a single site display mode shown in figure 16a where one parameter, for example SPaO₂ for site one is displayed to a multi-site display mode shown in figure 16b, where SPaO₂ for both sites are displayed. The alarm condition can be considered to indicate a worsening of a patient's condition. As such, it appears that Al-Ali provides a new teaching of some of the features found to be lacking at the time of allowance of claims 1-47 of the '223 patent, e.g. changing the parameters that are displayed based on a change in the patient's condition based on measured values of parameters. Therefore, Al-Ali provides a teaching of new technological features that were not present at the time of allowance of claims 1-47 of the '223 patent.

Since the teachings of Al-Ali are directly related to the subject matter considered as the basis for allowability of patent claims 1-47, a reasonable examiner would consider the evaluation of the Al-Ali to be important in determining the patentability of claims 1-47 of the '223 patent.

As such, it is agreed that the technological teachings of Al-Ali raise a substantial new question of patentability with respect to claims 1-47 that was not decided in a previous examination of the '223 patent.

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Kianl, Jarman, Nielsen, Healy, and Lepper are all utilized by the requester for reading on dependent claims. The dependent claims all depend on independent claims which have raised an SNQ as noted above. Therefore, Kianl, Jarman, Nielsen, Healy, and Lepper raises an SNQ through dependency.

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Service of Papers

After the filing of a request for reexamination by a third party requester, any document filed by either the patent owner or the third party requester must be served on the other party (or parties where two or more third party requester proceedings are merged) in the reexamination proceeding in the manner provided in 37 CFR 1.248. See 37 CFR 1.550(f).

Waiver of Right to File Patent Owner Statement

In a reexamination proceeding, Patent Owner may waive the right under 37 C.F.R. 1.530 to file a Patent Owner Statement. The document needs to contain a statement that Patent Owner waives the right under 37 C.F.R. 1.530 to file a Patent Owner Statement and proof of service in the manner provided by 37 C.F.R. 1.248, if the request for reexamination was made by a third party requester, see 37 C.F.R 1.550(f). The Patent Owner may consider using the following statement in a document waiving the right to file a Patent Owner Statement:

WAIVER OF RIGHT TO FILE PATENT OWNER STATEMENT

Patent Owner waives the right under 37 C.F.R. 1.530 to file a Patent Owner Statement.

Extensions of Time

Extensions of time under 37 CFR 1.136(a) will not be permitted in these proceedings because the provisions of 37 CFR 1.136 apply only to "an applicant" and

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not to parties in a reexamination proceeding. Additionally, 35 U.S.C. 305 requires that *ex parte* reexamination proceedings "will be conducted with special dispatch" (37 CFR 1.550(a)). Extensions of time in *ex parte* reexamination proceedings are provided for in 37 CFR 1.550(c).

Amendment in Reexamination Proceedings

Patent owner is notified that any proposed amendment to the specification and/or claims in this reexamination proceeding must comply with 37 CFR 1.530(d)-(j), must be formally presented pursuant to 37 CFR 1.52(a) and (b), and must contain any fees required by 37 CFR 1.20(c). See MPEP § 2250(IV) for examples to assist in the preparation of proper proposed amendments in reexamination proceedings.

Submissions

In order to insure full consideration of any amendments, affidavits or declarations or other documents as evidence of patentability, such documents must be submitted in response to the first Office action on the merits (which does not result in a close of prosecution). Submissions after the second Office action on the merits, which is intended to be a final action, will be governed by the requirements of 37 CFR 1.116, after final rejection and by 37 CFR 41.33 after appeal, which will be strictly enforced.

Notification of Concurrent Proceedings

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The patent owner is reminded of the continuing responsibility under 37 CFR 1.565(a), to apprise the Office of any litigation activity, or other prior or concurrent proceeding, involving Patent No. 8,190,223 throughout the course of this reexamination proceeding. Likewise, if present, the third party requester is also reminded of the ability to similarly apprise the Office of any such activity or proceeding throughout the course of this reexamination proceeding. See MPEP §§ 2207, 2282 and 2286.

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All correspondence relating to this *ex parte* reexamination proceeding should be directed as follows:

By U.S. Postal Service Mail to:

Mail Stop *Ex Parte* Reexam
ATTN: Central Reexamination Unit
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22312-1450

By EFS: Registered users may submit via the electronic filing system EFS-Web, at <https://efs.uspto.gov/efile/myportal/efs-registered>

By FAX to: (571) 273-9900
Central Reexamination Unit

By hand to: Customer Service Window
Randolph Building
401 Dulany St.
Alexandria, VA 22314

For EFS-Web transmissions, 37 CFR 1.8(a)(1)(i) (C) and (ii) states that correspondence (except for a request for reexamination and a corrected or replacement request for reexamination) will be considered timely filed if (a) it is transmitted via the Office's electronic filing system in accordance with 37 CFR 1.6(a)(4), and (b) includes a certificate of transmission for each piece of correspondence stating the date of transmission, which is prior to the expiration of the set period of time in the Office action.

Any inquiry concerning this communication or earlier communications from the Reexamination Legal Advisor or Examiner, or as to the status of this proceeding, should be directed to the Central Reexamination Unit at telephone number (571) 272-7705.

/Robert L. Nasser Jr./
Robert L. Nasser Jr.
CRU Primary Examiner
AU 3992
(571) 272-4731

Conferee: /FOF/

/Alexander J Kosowski/
Supervisory Patent Examiner, Art Unit 3992



UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
90/012,559	09/13/2012	8190223	403381US104RX	6710

20995 7590 12/03/2012
KNOBBE MARTENS OLSON & BEAR LLP
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EXAMINER

NASSER, ROBERT L

ART UNIT	PAPER NUMBER
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3992

MAIL DATE	DELIVERY MODE
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12/03/2012

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.



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(THIRD PARTY REQUESTER'S CORRESPONDENCE ADDRESS)

Tia D. Fenton

OBLON, SPIVAK, ET AL.

1940 Duke Street

Alexandria, Virginia 22314

***EX PARTE* REEXAMINATION COMMUNICATION TRANSMITTAL FORM**

REEXAMINATION CONTROL NO. 90/012,559.

PATENT NO. 8190223.

ART UNIT 3992.

Enclosed is a copy of the latest communication from the United States Patent and Trademark Office in the above identified *ex parte* reexamination proceeding (37 CFR 1.550(f)).

Where this copy is supplied after the reply by requester, 37 CFR 1.535, or the time for filing a reply has passed, no submission on behalf of the *ex parte* reexamination requester will be acknowledged or considered (37 CFR 1.550(g)).

Office Action in Ex Parte Reexamination	Control No. 90/012,559	Patent Under Reexamination 8190223
	Examiner ROBERT NASSER	Art Unit 3992

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

- a ☐ Responsive to the communication(s) filed on _____. b ☐ This action is made FINAL.
c ☒ A statement under 37 CFR 1.530 has not been received from the patent owner.

A shortened statutory period for response to this action is set to expire 2 month(s) from the mailing date of this letter. Failure to respond within the period for response will result in termination of the proceeding and issuance of an *ex parte* reexamination certificate in accordance with this action. 37 CFR 1.550(d). **EXTENSIONS OF TIME ARE GOVERNED BY 37 CFR 1.550(c).** If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☐ Notice of References Cited by Examiner, PTO-892. 3. ☐ Interview Summary, PTO-474.
2. ☐ Information Disclosure Statement, PTO/SB/08. 4. ☐ _____.

Part II SUMMARY OF ACTION

- 1a. ☒ Claims 1-47 are subject to reexamination.
1b. ☐ Claims _____ are not subject to reexamination.
2. ☐ Claims _____ have been canceled in the present reexamination proceeding.
3. ☒ Claims 7,13,21-26,28 and 45-47 are patentable and/or confirmed.
4. ☒ Claims 1-6, 8-12, 14-20, 27, 29-44 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ The drawings, filed on _____ are acceptable.
7. ☐ The proposed drawing correction, filed on _____ has been (7a) ☐ approved (7b) ☐ disapproved.
8. ☐ Acknowledgment is made of the priority claim under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of the certified copies have
1 ☐ been received.
2 ☐ not been received.
3 ☐ been filed in Application No. _____.
4 ☐ been filed in reexamination Control No. _____.
5 ☐ been received by the International Bureau in PCT application No. _____.
* See the attached detailed Office action for a list of the certified copies not received.
9. ☐ Since the proceeding appears to be in condition for issuance of an *ex parte* reexamination certificate except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte* Quayle, 1935 C.D. 11, 453 O.G. 213.
10. ☐ Other: _____

cc: Requester (if third party requester)

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Non-Final Rejection

This action addresses claims 1-47 of US Patent 8,190,223 to (Al-Ali et al (the '223 patent), for which a substantial new question of was deemed to have been raised by the request for Ex Parte Reexamination, filed 9/13/2012. This action is being issued in response to a voice mail received from Mr. Jerome Kessler on October 23, 2012, in which the Patent Owner verbally waived of Patent Owner Statement.

Interview Summary

Jerome Kessler left a voice mail for the examiner on 10/23/2012 indicating that the Patent Owner would waive the Patent Owner Statement.

Prior Art

U.S. Patent Application Publication 2002/0082488, filed December 21, 2001 and published June 27, 2002 to Al-Ali et al. ("A1-Ali").

U.S. Patent No. 6,658,276, filed February 12, 2002 and issued December 2, 2003 to Kianl et al. ("Kianl").

U.S. Patent No. 5,842,979, filed February 14, 1997 and issued December 1, 1998 to Jarman ("Jarman").

U.S. Patent No. 4,051,522, filed May 5, 1975 and issued September 27, 1977 to Healy et al. ("Healy").

U.S. Patent Application Publication 2003/0120164, filed December 20, 2001 and published June 26, 2003 to Nielsen ("Nielsen").

U.S. Patent No. 5,743,262, filed June 7, 1995 and issued April 28, 1998 to Lepper et al. ("Lepper").

Relevant Statutes

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Rejections

A. Claims 1-4 and 6, 15, 18-20, 27, 29, 31-38, and 42-44 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Al-Ali et al in view of Kiani.

As to claims 1 and 27, Al-Ali shows a pulse oximeter that measures parameters at multiple sites. Figures 16a and 16b show the display formats for the device of Al-Ali. Specifically, there is a first display area displaying the numerical values 1622 and 1632 of the parameters from the first site and a second display area displaying the values 1624 and 1634 from the second site. As seen in figure 16a, in single site display mode, the parameters from any one of the sites is displayed. The first and second display areas further include a common display area, the graphical display portion 1660. The display area switches from single site mode, displaying one of the parameters, to

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multiple site mode displaying the other parameter, in response to an alarm condition (see paragraph [0095]). The examiner notes that the claim that the display area changes from displaying one value to the other value based on an event, while Al-Ali changes from displaying one value to both values. The claim is written in open format, and as such, the claim is met if more than what in the claim is in the reference. Here, the reference changes from one parameter to the other parameter and additional display material, e.g. the first parameter. As such, it is the examiner's position that the claim is met. Finally, Al-Ali teaches that the switch in the display can be triggered by an alarm, which indicates a worsening of a patient's condition (e.g. moving from a non-alarm state to an alarm state). Al-Ali does not state that the alarm is based off of a threshold. However, Kiani teaches sounding an alarm when an upper or lower saturation threshold is exceeded. As such, it would have been obvious to modify Al-Ali to base the alarm on a threshold being exceeded, as it is merely the use of a well-known condition for such an alarm in an identical device.

The rejections of claims 2-6, 36, 42, and 43 are incorporated by reference herein, as presented on pages 19-21 of the request.

As to claim 15 and 18, the request notes the switch in the display is triggered based on an "alarm based on multiple site oxygen status parameters." Claim 15 requires that the switch be based on one of the parameters alarming and claim 18 requires that the switch be based on one parameter being more critical than the other. It is unclear whether the alarm in Al-Ali is based on a single parameter, or some combination of all of the parameters. However, Kiani teaches sounding alarms when

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the oxygen saturation exceeds a threshold, e.g. for individual parameters. As such, it would have been obvious to at least sound an oxygen saturation alarm at each site, to prevent injury and ensure that proper care is received.

The rejections of claims 19 and 20 are incorporated by reference herein, as presented on page 24 of the request.

The rejections of claims 29, 31-35, 37, 38, and 44 are incorporated by reference herein, as presented on pages 33-40 of the request.

B. Claims 8-10 and 39-41 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Al-Ali et al in view of Kiani, as applied to claims 1-4 and 6, 15, 18-20, 27, 29, 31-38, and 42-44, and further in view of Jarman.

Claims 8-10 and 39-41 are rejected in that it would have been obvious to modify Al-Ali and Kiani to also measure and display carbon monoxide and percent methemoglobin, for the reasons given on pages 43-49 of the request, which reasons are hereby incorporated by reference herein.

C. Claims 11, 12, 14, 16, 17, and 30 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Al-Ali et al in view of Kiani, as applied to claims 1-4 and 6, 15, 18-20, 27, 29, 31-38, and 42-44, and further in view of Healy.

The rejections of claims 11, 12, 14, 16, 17, and 30 are incorporated by reference herein, as presented on pages 50-55 of the request.

D. Claims 5 and 23 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Al-Ali et al in view of Kiani, as applied to claims 1-4 and 6, 15, 18-20, 27, 29, 31-38, and 42-44, and further in view of Nielsen.

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The rejections of claims 5 and 23 are incorporated by reference herein, as presented on pages 55-57 of the request, noting that Nielsen teaches measures oxygen saturation (spo2) together with invasive blood pressure.

STATEMENT OF REASONS FOR PATENTABILITY AND/OR CONFIRMATION

The following is an examiner's statement of reasons for patentability and/or confirmation of the claims found patentable in this reexamination proceeding:

Claims 7, 13, 21-26, 28, and 45-47 define over the art of record.

Claim 7 defines over the art of record in that none of the art measures glucose an another parameter, and switches the display, as claimed. The request cites Lepper, which is an optical glucose measuring device. The request asserts that it would have been obvious to modify Al-Ali to measure glucose, as it is the substitution of one known measurement element for another. The examiner disagrees. Al-Ali is a multi-parameter device that measures oxygen status of a patient. The entire disclosure is directed to measuring oxygen status. While Lepper teaches that optical methods can measure glucose, the request has made no connection between glucose and oxygen status of a patient and provided no reasons why one would measure glucose in an oxygen status monitoring device. Therefore, at best, the art establishes that one of ordinary skill can measure glucose optically, but provides no motivation or rationale to measure glucose in the device of Al-Ali. As such, claim 7 defines over the proposed rejection.

Claim 13 defines over the art of record in that none of the art changes the display size to indicate a change in the severity of the parameters. The request states that it

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would be a simple matter of design choice to change the size rather than the color.

However, there is not sufficient evidence to support this position. The only support is a statement by the requester. Bald assertions are insufficient to establish obviousness.

As such, claim 13 defines over the art of record.

Claims 21-26 define over the art in that none of the art replaces the display of a first measured value with a second measured value when a change in the measurement of the second value indicates a worsening of the patient's condition. As noted above, Al-Ali does not replace the first value, but switches from displaying the first value to displaying first and second values. He request asserts that while Al-Ali does not replace the value, this is nothing more than trivial and obvious substitution of design elements. The examiner disagrees, noting that there is not sufficient evidence to support this position. The only support is a statement by the requester. Bald assertions are insufficient to establish obviousness. As such, claim 21, and its dependent claims 22-26, define over Al-Ali alone, as presented in the request.

Claim 28 defines over the art in that none of the art shifts a position of the display of the second parameter with respect to the first parameter. The request again proposes that this is merely the trivial and obvious substitution of design elements. However, there is not sufficient evidence to support this position. The only support is a statement by the requester. Bald assertions are insufficient to establish obviousness. As such, claim 28 defines over Al-Ali alone, as presented in the request.

Claims 45-47 define over the art of record in that none of the art has the user activate a change for a predetermined duration with a first activation type and a

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undetermined duration with a second activation type. The request states that it would have been a matter of design choice to alter the length of display depending on the type of activation. However, there is not sufficient evidence to support this position. The only support is a statement by the requester. Bald assertions are insufficient to establish obviousness. As such, claims 45-47 define over the proposed combination.

Information Disclosure Statement

The Information Disclosure Statements (IDS) filed on 11/16/2012 and 11/19/2012 have been considered by the examiner. Documents which fail to constitute patents or printed publications or which are labeled “undated” on the SB/08B form have been lined through on the Form PTO/SB/08 (or PTO-1449) so as not to be published on the reexamination certificate. Those references initialed have been considered by the examiner to the extent noted below.

Per MPEP 2256, where patents, publications, and other such items of information are submitted by a party (patent owner or third party requester) in compliance with the requirements of the rules, the requisite degree of consideration to be given to such information will normally be limited by the degree to which the party filing the information citation has explained the content and relevance of the information. The initials of the examiner placed adjacent the citations on the form PTO/SB/08A and 08B or its equivalent, without an indication to the contrary in the record, do not signify that the information has been considered by the examiner any further than to the extent noted above.

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EXHIBIT 3



(11)

EP 2 305 104 B1

(12)

EUROPEAN PATENT SPECIFICATION

(45) Date of publication and mention
of the grant of the patent:
17.10.2018 Bulletin 2018/42

(51) Int Cl.:
A61B 5/00 (2006.01)

(21) Application number: **10193356.2**

(22) Date of filing: **01.03.2006**

(54) Multiple wavelength sensor drivers

Sensortreiber mit mehreren Wellenlängen

Pilotes de capteur à plusieurs longueurs d'onde

(84) Designated Contracting States:
**AT BE BG CH CY CZ DE DK EE ES FI FR GB GR
HU IE IS IT LI LT LU LV MC NL PL PT RO SE SI
SK TR**

(30) Priority: **01.03.2005 US 657596 P
01.03.2005 US 657759 P
01.03.2005 US 657268 P
01.03.2005 US 657281 P**

(43) Date of publication of application:
06.04.2011 Bulletin 2011/14

(62) Document number(s) of the earlier application(s) in
accordance with Art. 76 EPC:
06736800.1 / 1 860 996

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(56) References cited:
**US-A- 5 827 182 US-A- 6 165 005
US-A1- 2002 183 819 US-A1- 2004 147 823
US-B1- 6 184 521**

Note: Within nine months of the publication of the mention of the grant of the European patent in the European Patent Bulletin, any person may give notice to the European Patent Office of opposition to that patent, in accordance with the Implementing Regulations. Notice of opposition shall not be deemed to have been filed until the opposition fee has been paid. (Art. 99(1) European Patent Convention).

Description**BACKGROUND OF THE INVENTION**

[0001] Spectroscopy is a common technique for measuring the concentration of organic and some inorganic constituents of a solution. The theoretical basis of this technique is the Beer-Lambert law, which states that the concentration c_i of an absorbent in solution can be determined by the intensity of light transmitted through the solution, knowing the pathlength d_λ , the intensity of the incident light $I_{0,\lambda}$, and the extinction coefficient $\varepsilon_{i,\lambda}$ at a particular wavelength λ . In generalized form, the Beer-Lambert law is expressed as:

$$I_\lambda = I_{0,\lambda} e^{-d_\lambda \cdot \mu_{a,\lambda}} \quad (1)$$

$$\mu_{a,\lambda} = \sum_{i=1}^n \varepsilon_{i,\lambda} \cdot c_i \quad (2)$$

where $\mu_{a,\lambda}$ is the bulk absorption coefficient and represents the probability of absorption per unit length. The minimum number of discrete wavelengths that are required to solve EQS. 1-2 are the number of significant absorbers that are present in the solution.

[0002] A practical application of this technique is pulse oximetry, which utilizes a noninvasive sensor to measure oxygen saturation (SpO_2) and pulse rate. In general, the sensor has light emitting diodes (LEDs) that transmit optical radiation of red and infrared wavelengths into a tissue site and a detector that responds to the intensity of the optical radiation after absorption (e.g., by transmission or transreflectance) by pulsatile arterial blood flowing within the tissue site. Based on this response, a processor determines measurements for SpO_2 , pulse rate, and can output representative plethysmographic waveforms. Thus, "pulse oximetry" as used herein encompasses its broad ordinary meaning known to one of skill in the art, which includes at least those noninvasive procedures for measuring parameters of circulating blood through spectroscopy. Moreover, "plethysmograph" as used herein (commonly referred to as "photoplethysmograph"), encompasses its broad ordinary meaning known to one of skill in the art, which includes at least data representative of a change in the absorption of particular wavelengths of light as a function of the changes in body tissue resulting from pulsing blood. Pulse oximeters capable of reading through motion induced noise are available from Masimo Corporation ("Masimo") of Irvine, California. Moreover, portable and other oximeters capable of reading through motion induced noise are disclosed in at least U.S. Pat. Nos. 6,770,028, 6,658,276,

6,157,850, 6,002,952 5,769,785, and 5,758,644, which are owned by Masimo and are incorporated by reference herein. Such reading through motion oximeters have gained rapid acceptance in a wide variety of medical applications, including surgical wards, intensive care and neonatal units, general wards, home care, physical training, and virtually all types of monitoring scenarios.

SUMMARY OF THE INVENTION

[0003] There is a need to noninvasively measure multiple physiological parameters, other than, or in addition to, oxygen saturation and pulse rate. For example, hemoglobin species that are also significant under certain circumstances are carboxyhemoglobin and methemoglobin. Other blood parameters that may be measured to provide important clinical information are fractional oxygen saturation, total hemoglobin (Hbt), bilirubin and blood glucose, to name a few.

[0004] One aspect of a sensor driver is a cable capable of communicating signals between a physiological sensor and a monitor is a first row input, a first column input, a second row input and a second column input. The cable is capable of activating individual light emitters of an emitter array arranged in an electrical grid by driving at least one row drive line and at least one column drive line of the electrical grid. A first output combines the first row input and the first column input. A second output combines the second row input and the second column input. The inputs are adapted to connect to electrical grid drive lines of a monitor. Further, the outputs are adapted to connect to contacts of a physiological sensor having back-to-back configured LEDs in electrical communication with the contacts.

[0005] Another aspect of a sensor driver is an electrical grid configured to activate light emitting sources by addressing at least one row conductor and at least one column conductor. A first LED and a second LED are configured in a back-to-back arrangement so that a first contact is connected to a first LED cathode and a second LED anode and a second contact is connected to a first LED anode and a second LED cathode. The first contact is in communications with a first row conductor and a first column conductor. The second contact is in communications with a second row conductor and a second column conductor. Further, the first LED is activated by addressing the first row conductor and the second column conductor and the second LED is activated by addressing the second row conductor and the first column conductor.

[0006] A further aspect of a sensor driver is an electrical grid drive having at least a portion of the electrical grid drive communicated to a physiological sensor. The electrical grid drive is adapted to activate back-to-back configured LEDs. The invention is defined in the claims. All embodiments not falling under the scope of the claims are merely examples and are not part of the present invention.

BRIEF DESCRIPTION OF THE DRAWINGS**[0007]**

FIG. 1 is a perspective view of a physiological measurement system utilizing a multiple wavelength sensor;

FIGS. 2A-C are perspective views of multiple wavelength sensor embodiments;

FIG. 3 is a general block diagram of a multiple wavelength sensor and sensor controller;

FIG. 4 is an exploded perspective view of a multiple wavelength sensor embodiment;

FIG. 5 is a general block diagram of an emitter assembly;

FIG. 6 is a perspective view of an emitter assembly embodiment;

FIG. 7 is a general block diagram of an emitter array;

FIG. 8 is a schematic diagram of an emitter array embodiment;

FIG. 9 is a general block diagram of equalization;

FIGS. 10A-D are block diagrams of various equalization embodiments;

FIGS. 11A-C are perspective views of an emitter assembly incorporating various equalization embodiments;

FIG. 12 is a general block diagram of an emitter substrate;

FIGS. 13-14 are top and detailed side views of an emitter substrate embodiment;

FIG. 15-16 are top and bottom component layout views of an emitter substrate embodiment;

FIG. 17 is a schematic diagram of an emitter substrate embodiment;

FIG. 18 is a plan view of an inner layer of an emitter substrate embodiment;

FIG. 19 is a general block diagram of an interconnect assembly in relationship to other sensor assemblies;

FIG. 20 is a block diagram of an interconnect assembly embodiment;

FIG. 21 is a partially-exploded perspective view of a flex circuit assembly embodiment of an interconnect assembly;

FIG. 22 is a top plan view of a flex circuit;

FIG. 23 is an exploded perspective view of an emitter portion of a flex circuit assembly;

FIG. 24 is an exploded perspective view of a detector assembly embodiment;

FIGS. 25-26 are block diagrams of adjacent detector and stacked detector embodiments;

FIG. 27 is a block diagram of a finger clip embodiment of an attachment assembly;

FIG. 28 is a general block diagram of a detector pad;

FIGS. 29A-B are perspective views of detector pad embodiments;

FIGS. 30A-H are perspective bottom, perspective top, bottom, back, top, side cross sectional, side, and front cross sectional views of an emitter pad embodi-

ment;

FIGS. 31A-H are perspective bottom, perspective top, top, back, bottom, side cross sectional, side, and front cross sectional views of a detector pad embodiment;

FIGS. 32A-H are perspective bottom, perspective top, top, back, bottom, side cross sectional, side, and front cross sectional views of a shoe box;

FIGS. 33A-H are perspective bottom, perspective top, top, back, bottom, side cross sectional, side, and front cross sectional views of a slim-finger emitter pad embodiment;

FIGS. 34A-H are perspective bottom, perspective top, top, back, bottom, side cross sectional, side, and front cross sectional views of a slim-finger detector pad embodiment;

FIGS. 35A-B are plan and cross sectional views, respectively, of a spring assembly embodiment;

FIGS. 36A-C are top, perspective and side views of a finger clip spring;

FIGS. 37A-D are top, back, bottom, and side views of a spring plate;

FIGS. 38A-D are front cross sectional, bottom, front and side cross sectional views of an emitter-pad shell;

FIGS. 39A-D are back, top, front and side cross sectional views of a detector-pad shell;

FIG. 40 is a general block diagram of a monitor and a sensor;

FIGS. 41A-C are schematic diagrams of grid drive embodiments for a sensor having back-to-back diodes and an information element;

FIGS. 42 is a schematic diagrams of a grid drive embodiment for an information element;

FIGS. 43A-C are schematic diagrams for grid drive readable information elements;

FIGS. 44A-B are cross sectional and side cut away views of a sensor cable;

FIG. 45 is a block diagram of a sensor controller embodiment; and

FIG. 46 is a detailed exploded perspective view of a multiple wavelength sensor embodiment.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTSOverview

[0008] In this application, reference is made to many blood parameters. Some references that have common shorthand designations are referenced through such shorthand designations. For example, as used herein, HbCO designates carboxyhemoglobin, HbMet designates methemoglobin, and Hbt designates total hemoglobin. Other shorthand designations such as COHb, MetHb, and tHb are also common in the art for these same constituents. These constituents are generally reported in terms of a percentage, often referred to as sat-

uration, relative concentration or fractional saturation. Total hemoglobin is generally reported as a concentration in g/dL. The use of the particular shorthand designators presented in this application does not restrict the term to any particular manner in which the designated constituent is reported.

[0009] FIG. 1 illustrates a physiological measurement system 10 having a monitor 100 and a multiple wavelength sensor assembly 200 with enhanced measurement capabilities as compared with conventional pulse oximetry. The physiological measurement system 10 allows the monitoring of a person, including a patient. In particular, the multiple wavelength sensor assembly 200 allows the measurement of blood constituent and related parameters in addition to oxygen saturation and pulse rate. Alternatively, the multiple wavelength sensor assembly 200 allows the measurement of oxygen saturation and pulse rate with increased accuracy or robustness as compared with conventional pulse oximetry.

[0010] In one embodiment, the sensor assembly 200 is configured to plug into a monitor sensor port 110. Monitor keys 160 provide control over operating modes and alarms, to name a few. A display 170 provides readouts of measured parameters, such as oxygen saturation, pulse rate, HbCO and HbMet to name a few.

[0011] FIGS. 2A illustrates a multiple wavelength sensor assembly 200 having a sensor 400 adapted to attach to a tissue site, a sensor cable 4400 and a monitor connector 210. In one embodiment, the sensor 400 is incorporated into a reusable finger clip adapted to removably attach to, and transmit light through, a fingertip. The sensor cable 4400 and monitor connector 210 are integral to the sensor 400, as shown. In alternative embodiments, the sensor 400 may be configured separately from the cable 4400 and connector 210.

[0012] FIGS. 2B-C illustrate alternative sensor embodiments, including a sensor 401 (FIG. 2B) partially disposable and partially reusable (resposable) and utilizing an adhesive attachment mechanism. Also shown is a sensor 402 (FIG. 2C) being disposable and utilizing an adhesive attachment mechanism. In other embodiments, a sensor may be configured to attach to various tissue sites other than a finger, such as a foot or an ear. Also a sensor may be configured as a reflectance or transreflectance device that attaches to a forehead or other tissue surface.

[0013] FIG. 3 illustrates a sensor assembly 400 having an emitter assembly 500, a detector assembly 2400, an interconnect assembly 1900 and an attachment assembly 2700. The emitter assembly 500 responds to drive signals received from a sensor controller 4500 in the monitor 100 via the cable 4400 so as to transmit optical radiation having a plurality of wavelengths into a tissue site. The detector assembly 2400 provides a sensor signal to the monitor 100 via the cable 4400 in response to optical radiation received after attenuation by the tissue site. The interconnect assembly 1900 provides electrical communication between the cable 4400 and both the emitter assembly 500 and the detector assembly 2400.

The attachment assembly 2700 attaches the emitter assembly 500 and detector assembly 2400 to a tissue site, as described above. The emitter assembly 500 is described in further detail with respect to FIG. 5, below. The interconnect assembly 1900 is described in further detail with respect to FIG. 19, below. The detector assembly 2400 is described in further detail with respect to FIG. 24, below. The attachment assembly 2700 is described in further detail with respect to FIG. 27, below.

[0014] FIG. 4 illustrates a sensor 400 embodiment that removably attaches to a fingertip. The sensor 400 houses a multiple wavelength emitter assembly 500 and corresponding detector assembly 2400. A flex circuit assembly 1900 mounts the emitter and detector assemblies 500, 2400 and interconnects them to a multiwire sensor cable 4400. Advantageously, the sensor 400 is configured in several respects for both wearer comfort and parameter measurement performance. The flex circuit assembly 1900 is configured to mechanically decouple the cable 4400 wires from the emitter and detector assemblies 500, 2400 to reduce pad stiffness and wearer discomfort. The pads 3000, 3100 are mechanically decoupled from shells 3800, 3900 to increase flexibility and wearer comfort. A spring 3600 is configured in hinged shells 3800, 3900 so that the pivot point of the finger clip is well behind the fingertip, improving finger attachment and more evenly distributing the clip pressure along the finger.

[0015] As shown in FIG. 4, the detector pad 3100 is structured to properly position a fingertip in relationship to the detector assembly 2400. The pads have flaps that block ambient light. The detector assembly 2400 is housed in an enclosure so as to reduce light piping from the emitter assembly to the detector assembly without passing through fingertip tissue. These and other features are described in detail below. Specifically, emitter assembly embodiments are described with respect to FIGS. 5-18. Interconnect assembly embodiments, including the flexible circuit assembly 1900, are described with respect to FIGS. 19-23. Detector assembly embodiments are described with respect to FIGS. 24-26. Attachment assembly embodiments are described with respect to FIGS. 27-39.

Emitter Assembly

[0016] FIG. 5 illustrates an emitter assembly 500 having an emitter array 700, a substrate 1200 and equalization 900. The emitter array 700 has multiple light emitting sources, each activated by addressing at least one row and at least one column of an electrical grid. The light emitting sources are capable of transmitting optical radiation having multiple wavelengths. The equalization 900 accounts for differences in tissue attenuation of the optical radiation across the multiple wavelengths so as to at least reduce wavelength-dependent variations in detected intensity. The substrate 1200 provides a physical mount for the emitter array and emitter-related equalization and a connection between the emitter array and the

interconnection assembly. Advantageously, the substrate **1200** also provides a bulk temperature measurement so as to calculate the operating wavelengths for the light emitting sources. The emitter array **700** is described in further detail with respect to FIG. 7, below. Equalization is described in further detail with respect to FIG. 9, below. The substrate **1200** is described in further detail with respect to FIG. 12, below.

[0017] FIG. 6 illustrates an emitter assembly **500** embodiment having an emitter array **700**, an encapsulant **600**, an optical filter **1100** and a substrate **1200**. Various aspects of the emitter assembly **500** are described with respect to FIGS. 7-18, below. The emitter array **700** emits optical radiation having multiple wavelengths of predetermined nominal values, advantageously allowing multiple parameter measurements. In particular, the emitter array **700** has multiple light emitting diodes (LEDs) **710** that are physically arranged and electrically connected in an electrical grid to facilitate drive control, equalization, and minimization of optical pathlength differences at particular wavelengths. The optical filter **1100** is advantageously configured to provide intensity equalization across a specific LED subset. The substrate **1200** is configured to provide a bulk temperature of the emitter array **700** so as to better determine LED operating wavelengths.

Emitter Array

[0018] FIG. 7 illustrates an emitter array **700** having multiple light emitters (LE) **710** capable of emitting light **702** having multiple wavelengths into a tissue site **1**. Row drivers **4530** and column drivers **4560** are electrically connected to the light emitters **710** and activate one or more light emitters **710** by addressing at least one row **720** and at least one column **740** of an electrical grid. In one embodiment, the light emitters **710** each include a first contact **712** and a second contact **714**. The first contact **712** of a first subset **730** of light emitters is in communication with a first conductor **720** of the electrical grid. The second contact **714** of a second subset **750** of light emitters is in communication with a second conductor **740**. Each subset comprises at least two light emitters, and at least one of the light emitters of the first and second subsets **730**, **750** are not in common. A detector **2400** is capable of detecting the emitted light **702** and outputting a sensor signal **2500** responsive to the emitted light **702** after attenuation by the tissue site **1**. As such, the sensor signal **2500** is indicative of at least one physiological parameter corresponding to the tissue site **1**, as described above.

[0019] FIG. 8 illustrates an emitter array **700** having LEDs **801** connected within an electrical grid of n rows and m columns totaling $n + m$ drive lines **4501**, **4502**, where n and m integers greater than one. The electrical grid advantageously minimizes the number of drive lines required to activate the LEDs **801** while preserving flexibility to selectively activate individual LEDs **801** in any

sequence and multiple LEDs **801** simultaneously. The electrical grid also facilitates setting LED currents so as to control intensity at each wavelength, determining operating wavelengths and monitoring total grid current so as to limit power dissipation. The emitter array **700** is also physically configured in rows **810**. This physical organization facilitates clustering LEDs **801** according to wavelength so as to minimize pathlength variations and facilitates equalization of LED intensities.

[0020] As shown in FIG. 8, one embodiment of an emitter array **700** comprises up to sixteen LEDs **801** configured in an electrical grid of four rows **810** and four columns **820**. Each of the four row drive lines **4501** provide a common anode connection to four LEDs **801**, and each of the four column drive lines **4502** provide a common cathode connection to four LEDs **801**. Thus, the sixteen LEDs **801** are advantageously driven with only eight wires, including four anode drive lines **812** and four cathode drive lines **822**. This compares favorably to conventional common anode or cathode LED configurations, which require more drive lines. In a particular embodiment, the emitter array **700** is partially populated with eight LEDs having nominal wavelengths as shown in TABLE 1. Further, LEDs having wavelengths in the range of 610-630 nm are grouped together in the same row. The emitter array **700** is adapted to a physiological measurement system **10** (FIG. 1) for measuring H_bCO and/or $METHb$ in addition to S_pO_2 and pulse rate.

TABLE 1: Nominal LED Wavelengths

LED	λ	Row	Col
D1	630	1	1
D2	620	1	2
D3	610	1	3
D4		1	4
D5	700	2	1
D6	730	2	2
D7	660	2	3
D8	805	2	4
D9		3	1
D10		3	2
D11		3	3
D12	905	3	4
D13		4	1
D14		4	2
D15		4	3
D16		4	4

[0021] Also shown in FIG. 8, row drivers **4530** and column drivers **4560** located in the monitor **100** selectively

activate the LEDs **801**. In particular, row and column drivers **4530**, **4560** function together as switches to Vcc and current sinks, respectively, to activate LEDs and as switches to ground and Vcc, respectively, to deactivate LEDs. This push-pull drive configuration advantageously prevents parasitic current flow in deactivated LEDs. In a particular embodiment, only one row drive line **4501** is switched to Vcc at a time. One to four column drive lines **4502**, however, can be simultaneously switched to a current sink so as to simultaneously activate multiple LEDs within a particular row. Activation of two or more LEDs of the same wavelength facilitates intensity equalization, as described with respect to FIGS. **9-11**, below. LED drivers are described in further detail with respect to FIG. **45**, below.

[0022] Although an emitter assembly is described above with respect to an array of light emitters each configured to transmit optical radiation centered around a nominal wavelength, in another embodiment, an emitter assembly advantageously utilizes one or more tunable broadband light sources, including the use of filters to select the wavelength, so as to minimize wavelength-dependent pathlength differences from emitter to detector. In yet another emitter assembly embodiment, optical radiation from multiple emitters each configured to transmit optical radiation centered around a nominal wavelength is funneled to a tissue site point so as to minimize wavelength-dependent pathlength differences. This funneling may be accomplished with fiberoptics or mirrors, for example. In further embodiments, the LEDs **801** can be configured with alternative orientations with correspondingly different drivers among various other configurations of LEDs, drivers and interconnecting conductors.

Equalization

[0023] FIG. **9** illustrate a physiological parameter measurement system **10** having a controller **4500**, an emitter assembly **500**, a detector assembly **2400** and a front-end **4030**. The emitter assembly **500** is configured to transmit optical radiation having multiple wavelengths into the tissue site **1**. The detector assembly **2400** is configured to generate a sensor signal **2500** responsive to the optical radiation after tissue attenuation. The front-end **4030** conditions the sensor signal **2500** prior to analog-to-digital conversion (ADC).

[0024] FIG. **9** also generally illustrates equalization **900** in a physiological measurement system **10** operating on a tissue site **1**. Equalization encompasses features incorporated into the system **10** in order to provide a sensor signal **2500** that falls well within the dynamic range of the ADC across the entire spectrum of emitter wavelengths. In particular, equalization compensates for the imbalance in tissue light absorption due to Hb and HbO₂ **910**. Specifically, these blood constituents attenuate red wavelengths greater than IR wavelengths. Ideally, equalization **900** balances this unequal attenuation. Equalization **900** can be introduced anywhere in the system **10**

from the controller **4500** to front-end **4000** and can include compensatory attenuation versus wavelength, as shown, or compensatory amplification versus or both.

[0025] Equalization can be achieved to a limited extent by adjusting drive currents from the controller **4500** and front-end **4030** amplification accordingly to wavelength so as to compensate for tissue absorption characteristics. Signal demodulation constraints, however, limit the magnitude of these adjustments. Advantageously, equalization **900** is also provided along the optical path from emitters **500** to detector **2400**. Equalization embodiments are described in further detail with respect to FIGS. **10-11**, below.

[0026] FIGS. **10A-D** illustrate various equalization embodiments having an emitter array **700** adapted to transmit optical radiation into a tissue site **1** and a detector assembly **2400** adapted to generate a sensor signal **2500** responsive to the optical radiation after tissue attenuation. FIG. **10A** illustrates an optical filter **1100** that attenuates at least a portion of the optical radiation before it is transmitted into a tissue site **1**. In particular, the optical filter **1100** attenuates at least a portion of the IR wavelength spectrum of the optical radiation so as to approximate an equalization curve **900** (FIG. **9**). FIG. **10B** illustrates an optical filter **1100** that attenuates at least a portion of the optical radiation after it is attenuated by a tissue site **1**, where the optical filter **1100** approximates an equalization curve **900** (FIG. **9**).

[0027] FIG. **10C** illustrates an emitter array **700** where at least a portion of the emitter array generates one or more wavelengths from multiple light emitters **710** of the same wavelength. In particular, the same-wavelength light emitters **710** boost at least a portion of the red wavelength spectrum so as to approximately equalize the attenuation curves **910** (FIG. **9**). FIG. **10D** illustrates a detector assembly **2400** having multiple detectors **2610**, **2620** selected so as to equalize the attenuation curves **910** (FIG. **9**). To a limited extent, optical equalization can also be achieved by selection of particular emitter array **700** and detector **2400** components, e.g. LEDs having higher output intensities or detectors having higher sensitivities at red wavelengths. Although equalization embodiments are described above with respect to red and IR wavelengths, these equalization embodiments can be applied to equalize tissue characteristics across any portion of the optical spectrum.

[0028] FIGS. **11A-C** illustrates an optical filter **1100** for an emitter assembly **500** that advantageously provides optical equalization, as described above. LEDs within the emitter array **700** may be grouped according to output intensity or wavelength or both. Such a grouping facilitates equalization of LED intensity across the array. In particular, relatively low tissue absorption and/or relatively high output intensity LEDs can be grouped together under a relatively high attenuation optical filter. Likewise, relatively low tissue absorption and/or relatively low output intensity LEDs can be grouped together without an optical filter or under a relatively low or negligible atten-

uation optical filter. Further, high tissue absorption and/or low intensity LEDs can be grouped within the same row with one or more LEDs of the same wavelength being simultaneously activated, as described with respect to FIG. 10C, above. In general, there can be any number of LED groups and any number of LEDs within a group. There can also be any number of optical filters corresponding to the groups having a range of attenuation, including no optical filter and/or a "clear" filter having negligible attenuation.

[0029] As shown in FIGS. 11A-C, a filtering media may be advantageously added to an encapsulant that functions both as a cover to protect LEDs and bonding wires and as an optical filter 1100. In one embodiment, a filtering media 1100 encapsulates a select group of LEDs and a clear media 600 (FIG. 6) encapsulates the entire array 700 and the filtering media 1000 (FIG. 6). In a particular embodiment, corresponding to TABLE 1, above, five LEDs nominally emitting at 660-905 nm are encapsulated with both a filtering media 1100 and an overlying clear media 600 (FIG. 6), i.e. attenuated. In a particular embodiment, the filtering media 1100 is a 40:1 mixture of a clear encapsulant (EPO-TEK OG147-7) and an opaque encapsulate (EPO-TEK OG147) both available from Epoxy Technology, Inc., Billerica, MA. Three LEDs nominally emitting at 610-630 nm are only encapsulated with the clear media 600 (FIG. 6), i.e. unattenuated.

In alternative embodiments, individual LEDs may be singly or multiply encapsulated according to tissue absorption and/or output intensity. In other alternative embodiments, filtering media may be separately attachable optical filters or a combination of encapsulants and separately attachable optical filters. In a particular embodiment, the emitter assembly 500 has one or more notches along each side proximate the component end 1305 (FIG. 13) for retaining one or more clip-on optical filters.

Substrate

[0030] FIG. 12 illustrates light emitters 710 configured to transmit optical radiation 1201 having multiple wavelengths in response to corresponding drive currents 1210. A thermal mass 1220 is disposed proximate the emitters 710 so as to stabilize a bulk temperature 1202 for the emitters. A temperature sensor 1230 is thermally coupled to the thermal mass 1220, wherein the temperature sensor 1230 provides a temperature sensor output 1232 responsive to the bulk temperature 1202 so that the wavelengths are determinable as a function of the drive currents 1210 and the bulk temperature 1202.

[0031] In one embodiment, an operating wavelength λ_a of each light emitter 710 is determined according to EQ. 3

$$\lambda_a = f(T_b, I_{drive}, \sum I_{drive}) \quad (3)$$

where T_b is the bulk temperature, I_{drive} is the drive current for a particular light emitter, as determined by the sensor controller 4500 (FIG. 45), described below, and $\sum I_{drive}$ is the total drive current for all light emitters. In another embodiment, temperature sensors are configured to measure the temperature of each light emitter 710 and an operating wavelength λ_a of each light emitter 710 is determined according to EQ. 4

$$\lambda_a = f(T_a, I_{drive}, \sum I_{drive}) \quad (4)$$

where T_a is the temperature of a particular light emitter, I_{drive} is the drive current for that light emitter and $\sum I_{drive}$ is the total drive current for all light emitters.

[0032] In yet another embodiment, an operating wavelength for each light emitter is determined by measuring the junction voltage for each light emitter 710. In a further embodiment, the temperature of each light emitter 710 is controlled, such as by one or more Peltier cells coupled to each light emitter 710, and an operating wavelength for each light emitter 710 is determined as a function of the resulting controlled temperature or temperatures. In other embodiments, the operating wavelength for each light emitter 710 is determined directly, for example by attaching a charge coupled device (CCD) to each light emitter or by attaching a fiberoptic to each light emitter and coupling the fiberoptics to a wavelength measuring device, to name a few.

[0033] FIGS. 13-18 illustrate one embodiment of a substrate 1200 configured to provide thermal conductivity between an emitter array 700 (FIG. 8) and a thermistor 1540 (FIG. 16). In this manner, the resistance of the thermistor 1540 (FIG. 16) can be measured in order to determine the bulk temperature of LEDs 801 (FIG. 8) mounted on the substrate 1200. The substrate 1200 is also configured with a relatively significant thermal mass, which stabilizes and normalizes the bulk temperature so that the thermistor measurement of bulk temperature is meaningful.

[0034] FIGS. 13-14 illustrate a substrate 1200 having a component side 1301, a solder side 1302, a component end 1305 and a connector end 1306. Alignment notches 1310 are disposed between the ends 1305, 1306. The substrate 1200 further has a component layer 1401, inner layers 1402-1405 and a solder layer 1406. The inner layers 1402-1405, e.g. inner layer 1402 (FIG. 18), have substantial metallized areas 1411 that provide a thermal mass 1220 (FIG. 12) to stabilize a bulk temperature for the emitter array 700 (FIG. 12). The metallized areas 1411 also function to interconnect component pads 1510 and wire bond pads 1520 (FIG. 15) to the connector 1530.

[0035] FIGS. 15-16 illustrate a substrate 1200 having component pads 1510 and wire bond pads 1520 at a component end 1305. The component pads 1510 mount and electrically connect a first side (anode or cathode)

of the LEDs **801** (FIG. **8**) to the substrate **1200**. Wire bond pads **1520** electrically connect a second side (cathode or anode) of the LEDs **801** (FIG. **8**) to the substrate **1200**. The connector end **1306** has a connector **1530** with connector pads **1532**, **1534** that mount and electrically connect the emitter assembly **500** (FIG. **23**), including the substrate **1200**, to the flex circuit **2200** (FIG. **22**). Substrate layers **1401-1406** (FIG. **14**) have traces that electrically connect the component pads **1510** and wire bond pads **1520** to the connector **1532-1534**. A thermistor **1540** is mounted to thermistor pads **1550** at the component end **1305**, which are also electrically connected with traces to the connector **1530**. Plated thru holes electrically connect the connector pads **1532**, **1534** on the component end and solder sides **1301**, **1302**, respectively.

[0036] FIG. **17** illustrates the electrical layout of a substrate **1200**. A portion of the LEDs **801**, including D1-D4 and D13-D16 have cathodes physically and electrically connected to component pads **1510** (FIG. **15**) and corresponding anodes wire bonded to wire bond pads **1520**. Another portion of the LEDs **801**, including D5-D8 and D9-D12, have anodes physically and electrically connected to component pads **1510** (FIG. **15**) and corresponding cathodes wire bonded to wire bond pads **1520**. The connector **1530** has row pinouts J21-J24, column pinouts J31-J34 and thermistor pinouts J40-J41 for the LEDs **801** and thermistor **1540**.

Interconnect Assembly

[0037] FIG. **19** illustrates an interconnect assembly **1900** that mounts the emitter assembly **500** and detector assembly **2400**, connects to the sensor cable **4400** and provides electrical communications between the cable and each of the emitter assembly **500** and detector assembly **2400**. In one embodiment, the interconnect assembly **1900** is incorporated with the attachment assembly **2700**, which holds the emitter and detector assemblies to a tissue site. An interconnect assembly embodiment utilizing a flexible (flex) circuit is described with respect to FIGS. **20-24**, below.

[0038] FIG. **20** illustrates an interconnect assembly **1900** embodiment having a circuit substrate **2200**, an emitter mount **2210**, a detector mount **2220** and a cable connector **2230**. The emitter mount **2210**, detector mount **2220** and cable connector **2230** are disposed on the circuit substrate **2200**. The emitter mount **2210** is adapted to mount an emitter assembly **500** having multiple emitters. The detector mount **2220** is adapted to mount a detector assembly **2400** having a detector. The cable connector **2230** is adapted to attach a sensor cable **4400**. A first plurality of conductors **2040** disposed on the circuit substrate **2200** electrically interconnects the emitter mount **2210** and the cable connector **2230**. A second plurality of conductors **2050** disposed on the circuit substrate **2200** electrically interconnects the detector mount **2220** and the cable connector **2230**. A decoupling **2060** disposed proximate the cable connector **2230** substan-

tially mechanically isolates the cable connector **2230** from both the emitter mount **2210** and the detector mount **2220** so that sensor cable stiffness is not translated to the emitter assembly **500** or the detector assembly **2400**. A shield **2070** is adapted to fold over and shield one or more wires or pairs of wires of the sensor cable **4400**.

[0039] FIG. **21** illustrates a flex circuit assembly **1900** having a flex circuit **2200**, an emitter assembly **500** and a detector assembly **2400**, which is configured to terminate the sensor end of a sensor cable **4400**. The flex circuit assembly **1900** advantageously provides a structure that electrically connects yet mechanically isolates the sensor cable **4400**, the emitter assembly **500** and the detector assembly **2400**. As a result, the mechanical stiffness of the sensor cable **4400** is not translated to the sensor pads **3000**, **3100** (FIGS. **30-31**), allowing a comfortable finger attachment for the sensor **200** (FIG. **1**). In particular, the emitter assembly **500** and detector assembly **2400** are mounted to opposite ends **2201**, **2202** (FIG. **22**) of an elongated flex circuit **2200**. The sensor cable **4400** is mounted to a cable connector **2230** extending from a middle portion of the flex circuit **2200**. Detector wires **4470** are shielded at the flex circuit junction by a fold-over conductive ink flap **2240**, which is connected to a cable inner shield **4450**. The flex circuit **2200** is described in further detail with respect to FIG. **22**. The emitter portion of the flex circuit assembly **1900** is described in further detail with respect to FIG. **23**. The detector assembly **2400** is described with respect to FIG. **24**. The sensor cable **4400** is described with respect to FIGS. **44A-B**, below.

[0040] FIG. **22** illustrates a sensor flex circuit **2200** having an emitter end **2201**, a detector end **2202**, an elongated interconnect **2204**, **2206** between the ends **2201**, **2202** and a cable connector **2230** extending from the interconnect **2204**, **2206**. The emitter end **2201** forms a "head" having emitter solder pads **2210** for attaching the emitter assembly **500** (FIG. **6**) and mounting ears **2214** for attaching to the emitter pad **3000** (FIG. **30B**), as described below. The detector end **2202** has detector solder pads for attaching the detector **2410** (FIG. **24**). The interconnect **2204** between the emitter end **2201** and the cable connector **2230** forms a "neck," and the interconnect **2206** between the detector end **2202** and the cable connector **2230** forms a "tail." The cable connector **2230** forms "wings" that extend from the interconnect **2204**, **2206** between the neck **2204** and tail **2206**. A conductive ink flap **2240** connects to the cable inner shield **4450** (FIGS. **44A-B**) and folds over to shield the detector wires **4470** (FIGS. **44A-B**) soldered to the detector wire pads **2236**. The outer wire pads **2238** connect to the remaining cable wires **4430** (FIGS. **44A-B**). The flex circuit **2200** has top coverlay, top ink, inner coverlay, trace, trace base, bottom ink and bottom coverlay layers.

[0041] The flex circuit **2200** advantageously provides a connection between a multiple wire sensor cable **4400** (FIGS. **44A-B**), a multiple wavelength emitter assembly **500** (FIG. **6**) and a detector assembly **2400** (FIG. **24**)

without rendering the emitter and detector assemblies unwieldy and stiff. In particular, the wings **2230** provide a relatively large solder pad area **2232** that is narrowed at the neck **2204** and tail **2206** to mechanically isolate the cable **4400** (FIGS. **44A-B**) from the remainder of the flex circuit **2200**. Further, the neck **2206** is folded (see FIG. **4**) for installation in the emitter pad **3000** (FIGS. **30A-H**) and acts as a flexible spring to further mechanically isolate the cable **4400** (FIGS. **44A-B**) from the emitter assembly **500** (FIG. **4**). The tail **2206** provides an integrated connectivity path between the detector assembly **2400** (FIG. **24**) mounted in the detector pad **3100** (FIGS. **31A-H**) and the cable connector **2230** mounted in the opposite emitter pad **3000** (FIGS. **30A-H**).

[0042] FIG. **23** illustrates the emitter portion of the flex circuit assembly **1900** (FIG. **21**) having the emitter assembly **500**. The emitter assembly connector **1530** is attached to the emitter end **2210** of the flex circuit **2200** (FIG. **22**). In particular, reflow solder **2330** connects thru hole pads **1532**, **1534** of the emitter assembly **500** to corresponding emitter pads **2310** of the flex circuit **2200** (FIG. **22**).

[0043] FIG. **24** illustrates a detector assembly **2400** including a detector **2410**, solder pads **2420**, copper mesh tape **2430**, an EMI shield **2440** and foil **2450**. The detector **2410** is soldered **2460** chip side down to detector solder pads **2420** of the flex circuit **2200**. The detector solder joint and detector ground pads **2420** are wrapped with the Kapton tape **2470**. EMI shield tabs **2442** are folded onto the detector pads **2420** and soldered. The EMI shield walls are folded around the detector **2410** and the remaining tabs **2442** are soldered to the back of the EMI shield **2440**. The copper mesh tape **2430** is cut to size and the shielded detector and flex circuit solder joint are wrapped with the copper mesh tape **2430**. The foil **2450** is cut to size with a predetermined aperture **2452**. The foil **2450** is wrapped around shielded detector with the foil side in and the aperture **2452** is aligned with the EMI shield grid **2444**.

Detector Assembly

[0044] FIG. **25** illustrates an alternative detector assembly **2400** embodiment having adjacent detectors. Optical radiation having multiple wavelengths generated by emitters **700** is transmitted into a tissue site **1**. Optical radiation at a first set of wavelengths is detected by a first detector **2510**, such as, for example, a Si detector. Optical radiation at a second set of wavelengths is detected by a second detector **2520**, such as, for example, a GaAs detector.

[0045] FIG. **26** illustrates another alternative detector assembly **2400** embodiment having stacked detectors coaxial along a light path. Optical radiation having multiple wavelengths generated by emitters **700** is transmitted into a tissue site **1**. Optical radiation at a first set of wavelengths is detected by a first detector **2610**. Optical radiation at a second set of wavelengths passes through

the first detector **2610** and is detected by a second detector **2620**. In a particular embodiment, a silicon (Si) detector and a gallium arsenide (GaAs) detector are used. The Si detector is placed on top of the GaAs detector so that light must pass through the Si detector before reaching the GaAs detector. The Si detector can be placed directly on top of the GaAs detector or the Si and GaAs detector can be separated by some other medium, such as a transparent medium or air. In another particular embodiment, a germanium detector is used instead of the GaAs detector. Advantageously, the stacked detector arrangement minimizes error caused by pathlength differences as compared with the adjacent detector embodiment.

Finger Clip

[0046] FIG. **27** illustrates a finger clip embodiment **2700** of a physiological sensor attachment assembly. The finger clip **2700** is configured to removably attach an emitter assembly **500** (FIG. **6**) and detector assembly **2400** (FIG. **24**), interconnected by a flex circuit assembly **1900**, to a fingertip. The finger clip **2700** has an emitter shell **3800**, an emitter pad **3000**, a detector pad **2800** and a detector shell **3900**. The emitter shell **3800** and the detector shell **3900** are rotatably connected and urged together by the spring assembly **3500**. The emitter pad **3000** is fixedly retained by the emitter shell. The emitter assembly **500** (FIG. **6**) is mounted proximate the emitter pad **3000** and adapted to transmit optical radiation having a plurality of wavelengths into fingertip tissue. The detector pad **2800** is fixedly retained by the detector shell **3900**. The detector assembly **2400** is mounted proximate the detector pad **2800** and adapted to receive the optical radiation after attenuation by fingertip tissue.

[0047] FIG. **28** illustrates a detector pad **2800** advantageously configured to position and comfortably maintain a fingertip relative to a detector assembly for accurate sensor measurements. In particular, the detector pad has fingertip positioning features including a guide **2810**, a contour **2820** and a stop **2830**. The guide **2810** is raised from the pad surface **2803** and narrows as the guide **2810** extends from a first end **2801** to a second end **2802** so as to increasingly conform to a fingertip as a fingertip is inserted along the pad surface **2803** from the first end **2801**. The contour **2820** has an indentation defined along the pad surface **2803** generally shaped to conform to a fingertip positioned over a detector aperture **2840** located within the contour **2820**. The stop **2830** is raised from the pad surface **2803** so as to block the end of a finger from inserting beyond the second end **2802**. FIGS. **29A-B** illustrate detector pad embodiments **3100**, **3400** each having a guide **2810**, a contour **2820** and a stop **2830**, described in further detail with respect to FIGS. **31** and **34**, respectively.

[0048] FIGS. **30A-H** illustrate an emitter pad **3000** having emitter pad flaps **3010**, an emitter window **3020**, mounting pins **3030**, an emitter assembly cavity **3040**,

isolation notches **3050**, a flex circuit notch **3070** and a cable notch **3080**. The emitter pad flaps **3010** overlap with detector pad flaps **3110** (FIGS. **31A-H**) to block ambient light. The emitter window **3020** provides an optical path from the emitter array **700** (FIG. **8**) to a tissue site. The mounting pins **3030** accommodate apertures in the flex circuit mounting ears **2214** (FIG. **22**), and the cavity **3040** accommodates the emitter assembly **500** (FIG. **21**). Isolation notches **3050** mechanically decouple the shell attachment **3060** from the remainder of the emitter pad **3000**. The flex circuit notch **3070** accommodates the flex circuit tail **2206** (FIG. **22**) routed to the detector pad **3100** (FIGS. **31A-H**). The cable notch **3080** accommodates the sensor cable **4400** (FIGS. **44A-B**). FIGS. **33A-H** illustrate an alternative slim finger emitter pad **3300** embodiment.

[0049] FIGS. **31A-H** illustrate a detector pad **3100** having detector pad flaps **3110**, a shoe box cavity **3120** and isolation notches **3150**. The detector pad flaps **3110** overlap with emitter pad flaps **3010** (FIGS. **30A-H**), interleaving to block ambient light. The shoe box cavity **3120** accommodates a shoe box **3200** (FIG. **32A-H**) described below. Isolation notches **3150** mechanically decouple the attachment points **3160** from the remainder of the detector pad **3100**. FIGS. **34A-H** illustrate an alternative slim finger detector pad **3400** embodiment.

[0050] FIGS. **32A-H** illustrate a shoe box **3200** that accommodates the detector assembly **2400** (FIG. **24**). A detector window **3210** provides an optical path from a tissue site to the detector **2410** (FIG. **24**). A flex circuit notch **3220** accommodates the flex circuit tail **2206** (FIG. **22**) routed from the emitter pad **3000** (FIGS. **30A-H**). In one embodiment, the shoe box **3200** is colored black or other substantially light absorbing color and the emitter pad **3000** and detector pad **3100** are each colored white or other substantially light reflecting color.

[0051] FIGS. **35-37** illustrate a spring assembly **3500** having a spring **3600** configured to urge together an emitter shell **3800** (FIG. **46**) and a detector shell **3900**. The detector shell is rotatably connected to the emitter shell. The spring is disposed between the shells **3800**, **3900** and adapted to create a pivot point along a finger gripped between the shells that is substantially behind the fingertip. This advantageously allows the shell hinge **3810**, **3910** (FIGS. **38-39**) to expand so as to distribute finger clip force along the inserted finger, comfortably keeping the fingertip in position over the detector without excessive force.

[0052] As shown in FIGS **36A-C**, the spring **3600** has coils **3610**, an emitter shell leg **3620** and a detector shell leg **3630**. The emitter shell leg **3620** presses against the emitter shell **3800** (FIGS. **38A-D**) proximate a grip **3820** (FIGS. **38A-D**). The detector shell legs **3630** extend along the detector shell **3900** (FIGS. **39A-D**) to a spring plate **3700** (FIGS. **37A-D**) attachment point. The coil **3610** is secured by hinge pins **410** (FIG. **46**) and is configured to wind as the finger clip is opened, reducing its diameter and stress accordingly.

[0053] As shown in FIGS. **37A-D** the spring plate **3700** has attachment apertures **3710**, spring leg slots **3720**, and a shelf **3730**. The attachment apertures **3710** accept corresponding shell posts **3930** (FIGS. **39A-D**) so as to secure the spring plate **3700** to the detector shell **3900** (FIG. **39A-D**). Spring legs **3630** (FIG. **36A-C**) are slidably anchored to the detector shell **3900** (FIG. **39A-D**) by the shelf **3730**, advantageously allowing the combination of spring **3600**, shells **3800**, **3900** and hinges **3810**, **3910** to adjust to various finger sizes and shapes.

[0054] FIGS. **38-39** illustrate the emitter and detector shells **3800**, **3900**, respectively, having hinges **3810**, **3910** and grips **3820**, **3920**. Hinge apertures **3812**, **3912** accept hinge pins **410** (FIG. **46**) so as to create a finger clip. The detector shell hinge aperture **3912** is elongated, allowing the hinge to expand to accommodate a finger.

Monitor And Sensor

[0055] FIG. **40** illustrates a monitor **100** and a corresponding sensor assembly **200**, as described generally with respect to FIGS. **1-3**, above. The sensor assembly **200** has a sensor **400** and a sensor cable **4400**. The sensor **400** houses an emitter assembly **500** having emitters responsive to drivers within a sensor controller **4500** so as to transmit optical radiation into a tissue site. The sensor **400** also houses a detector assembly **2400** that provides a sensor signal **2500** responsive to the optical radiation after tissue attenuation. The sensor signal **2500** is filtered, amplified, sampled and digitized by the front-end **4030** and input to a DSP (digital signal processor) **4040**, which also commands the sensor controller **4500**. The sensor cable **4400** electrically communicates drive signals from the sensor controller **4500** to the emitter assembly **500** and a sensor signal **2500** from the detector assembly **2400** to the front-end **4030**. The sensor cable **4400** has a monitor connector **210** that plugs into a monitor sensor port **110**.

[0056] In one embodiment, the monitor **100** also has a reader **4020** capable of obtaining information from an information element (IE) in the sensor assembly **200** and transferring that information to the DSP **4040**, to another processor or component within the monitor **100**, or to an external component or device that is at least temporarily in communication with the monitor **100**. In an alternative embodiment, the reader function is incorporated within the DSP **4040**, utilizing one or more of DSP I/O, ADC, DAC features and corresponding processing routines, as examples.

[0057] In one embodiment, the monitor connector **210** houses the information element **4000**, which may be a memory device or other active or passive electrical component. In a particular embodiment, the information element **4000** is an EPROM, or other programmable memory, or an EEPROM, or other reprogrammable memory, or both. In an alternative embodiment, the information element **4000** is housed within the sensor **400**, or an information element **4000** is housed within both the monitor

connector **4000** and the sensor **400**. In yet another embodiment, the emitter assembly **500** has an information element **4000**, which is read in response to one or more drive signals from the sensor controller **4500**, as described with respect to FIGS. **41-43**, below. In a further embodiment, a memory information element is incorporated into the emitter array **700** (FIG. **8**) and has characterization information relating to the LEDs **801** (FIG. **8**). In one advantageous embodiment, trend data relating to slowly varying parameters, such as perfusion index, HbCO or METHb, to name a few, are stored in an IE memory device, such as EEPROM.

Back-to-Back LEDs

[0058] FIGS. **41-43** illustrate alternative sensor embodiments. A sensor controller **4500** configured to activate an emitter array **700** (FIG. **7**) arranged in an electrical grid, is described with respect to FIG. **7**, above. Advantageously, a sensor controller **4500** so configured is also capable of driving a conventional two-wavelength (red and IR) sensor **4100** having back-to-back LEDs **4110**, **4120** or an information element **4300** or both.

[0059] FIG. **41A** illustrates a sensor **4100** having an electrical grid **4130** configured to activate light emitting sources by addressing at least one row conductor and at least one column conductor. A first LED **4110** and a second LED **4120** are configured in a back-to-back arrangement so that a first contact **4152** is connected to a first LED **4110** cathode and a second LED **4120** anode and a second contact **4154** is connected to a first LED **4110** anode and a second LED **4120** cathode. The first contact **4152** is in communications with a first row conductor **4132** and a first column conductor **4134**. The second contact is in communications with a second row conductor **4136** and a second column conductor **4138**. The first LED **4110** is activated by addressing the first row conductor **4132** and the second column conductor **4138**. The second LED **4120** is activated by addressing the second row conductor **4136** and the first column conductor **4134**.

[0060] FIG. **41B** illustrates a sensor cable **4400** embodiment capable of communicating signals between a monitor **100** and a sensor **4100**. The cable **4400** has a first row input **4132**, a first column input **4134**, a second row input **4136** and a second column input **4138**. A first output **4152** combines the first row input **4132** and the first column input **4134**. A second output **4154** combines a second row input **4136** and second column input **4138**.

[0061] FIG. **41C** illustrates a monitor **100** capable of communicating drive signals to a sensor **4100**. The monitor **4400** has a first row signal **4132**, a first column signal **4134**, a second row signal **4136** and a second column signal **4138**. A first output signal **4152** combines the first row signal **4132** and the first column signal **4134**. A second output signal **4154** combines a second row signal **4136** and second column signal **4138**.

Information Elements

[0062] FIGS. **42-43** illustrate information element **4200-4300** embodiments in communications with emitter array drivers configured to activate light emitters connected in an electrical grid. The information elements are configured to provide information as DC values, AC values or a combination of DC and AC values in response corresponding DC, AC or combination DC and AC electrical grid drive signals. FIG. **42** illustrates information element embodiment **4200** advantageously driven directly by an electrical grid having rows **710** and columns **720**. In particular, the information element **4200** has a series connected resistor R_2 **4210** and diode **4220** connected between a row line **710** and a column line **720** of an electrical grid. In this manner, the resistor R_2 value can be read in a similar manner that LEDs **810** (FIG. **8**) are activated. The diode **4220** is oriented, e.g. anode to row and cathode to column as the LEDs so as to prevent parasitic currents from unwanted activation of LEDs **810** (FIG. **8**).

[0063] FIGS. **43A-C** illustrate other embodiments where the value of R_1 is read with a DC grid drive current and a corresponding grid output voltage level. In other particular embodiments, the combined values of R_1 , R_2 and C or, alternatively, R_1 , R_2 and L are read with a varying (AC) grid drive currents and a corresponding grid output voltage waveform. As one example, a step in grid drive current is used to determine component values from the time constant of a corresponding rise in grid voltage. As another example, a sinusoidal grid drive current is used to determine component values from the magnitude or phase or both of a corresponding sinusoidal grid voltage. The component values determined by DC or AC electrical grid drive currents can represent sensor types, authorized suppliers or manufacturers, emitter wavelengths among others. Further, a diode D (FIG. **43C**) can be used to provide one information element reading R_1 at one drive level or polarity and another information element reading, combining R_1 and R_2 , at a second drive level or polarity, i.e. when the diode is forward biased.

[0064] Passive information element **4300** embodiments may include any of various combinations of resistors, capacitors or inductors connected in series and parallel, for example. Other information element **4300** embodiments connected to an electrical grid and read utilizing emitter array drivers incorporate other passive components, active components or memory components, alone or in combination, including transistor networks, PROMs, ROMs, EPROMs, EEPROMs, gate arrays and PLAs to name a few.

Sensor Cable

[0065] FIGS. **44A-B** illustrate a sensor cable **4400** having an outer jacket **4410**, an outer shield **4420**, multiple outer wires **4430**, an inner jacket **4440**, an inner shield **4450**, a conductive polymer **4460** and an inner twisted

wire pair **4470**. The outer wires **4430** are advantageously configured to compactly carry multiple drive signals to the emitter array **700** (FIG. 7). In one embodiment, there are twelve outer wires **4430** corresponding to four anode drive signals **4501** (FIG. 45), four cathode drive signals **4502** (FIG. 45), two thermistor pinouts **1450** (FIG. 15) and two spares. The inner twisted wire pair **4470** corresponds to the sensor signal **2500** (FIG. 25) and is extruded within the conductive polymer **4460** so as to reduce triboelectric noise. The shields **4420**, **4450** and the twisted pair **4470** boost EMI and crosstalk immunity for the sensor signal **2500** (FIG. 25).

Controller

[0066] FIG. 45 illustrates a sensor controller **4500** located in the monitor **100** (FIG. 1) and configured to provide anode drive signals **4501** and cathode drive signals **4502** to the emitter array **700** (FIG. 7). The DSP (digital signal processor) **4040**, which performs signal processing functions for the monitor, also provides commands **4042** to the sensor controller **4500**. These commands determine drive signal **4501**, **4502** levels and timing. The sensor controller **4500** has a command register **4510**, an anode selector **4520**, anode drivers **4530**, current DACs (digital-to-analog converters) **4540**, a current multiplexer **4550**, cathode drivers **4560**, a current meter **4570** and a current limiter **4580**. The command register **4510** provides control signals responsive to the DSP commands **4042**. In one embodiment, the command register **4510** is a shift register that loads serial command data **4042** from the DSP **4040** and synchronously sets output bits that select or enable various functions within the sensor controller **4500**, as described below.

[0067] As shown in FIG. 45, the anode selector **4520** is responsive to anode select **4516** inputs from the command register **4510** that determine which emitter array row **810** (FIG. 8) is active. Accordingly, the anode selector **4520** sets one of the anode on **4522** outputs to the anode drivers **4530**, which pulls up to Vcc one of the anode outputs **4501** to the emitter array **700** (FIG. 8).

[0068] Also shown in FIG. 45, the current DACs **4540** are responsive to command register data **4519** that determines the currents through each emitter array column **820** (FIG. 8). In one embodiment, there are four, 12-bit DACs associated with each emitter array column **820** (FIG. 8), sixteen DACs in total. That is, there are four DAC outputs **4542** associated with each emitter array column **820** (FIG. 8) corresponding to the currents associated with each row **810** (FIG. 8) along that column **820** (FIG. 8). In a particular embodiment, all sixteen DACs **4540** are organized as a single shift register, and the command register **4510** serially clocks DAC data **4519** into the DACs **4540**. A current multiplexer **4550** is responsive to cathode on **4518** inputs from the command register **4510** and anode on **4522** inputs from the anode selector **4520** so as to convert the appropriate DAC outputs **4542** to current set **4552** inputs to the cathode driv-

ers **4560**. The cathode drivers **4560** are responsive to the current set **4552** inputs to pull down to ground one to four of the cathode outputs **4502** to the emitter array **700** (FIG. 8).

[0069] The current meter **4570** outputs a current measure **4572** that indicates the total LED current driving the emitter array **700** (FIG. 8). The current limiter **4580** is responsive to the current measure **4572** and limits specified by the command register **4510** so as to prevent excessive power dissipation by the emitter array **700** (FIG. 8). The current limiter **4580** provides an enable **4582** output to the anode selector **4520**. A Hi Limit **4512** input specifies the higher of two preset current limits. The current limiter **4580** latches the enable **4582** output in an off condition when the current limit is exceeded, disabling the anode selector **4520**. A trip reset **4514** input resets the enable **4582** output to re-enable the anode selector **4520**.

Sensor Assembly

[0070] As shown in FIG. 46, the sensor **400** has an emitter shell **3800**, an emitter pad **3000**, a flex circuit assembly **2200**, a detector pad **3100** and a detector shell **3900**. A sensor cable **4400** attaches to the flex circuit assembly **2200**, which includes a flex circuit **2100**, an emitter assembly **500** and a detector assembly **2400**. The portion of the flex circuit assembly **2200** having the sensor cable **4400** attachment and emitter assembly **500** is housed by the emitter shell **3800** and emitter pad **3000**. The portion of the flex circuit assembly **2200** having the detector assembly **2400** is housed by the detector shell **3900** and detector pad **3100**. In particular, the detector assembly **2400** inserts into a shoe **3200**, and the shoe **3200** inserts into the detector pad **3100**. The emitter shell **3800** and detector shell **3900** are fastened by and rotate about hinge pins **410**, which insert through coils of a spring **3600**. The spring **3600** is held to the detector shell **3900** with a spring plate **3700**. A finger stop **450** attaches to the detector shell. In one embodiment, a silicon adhesive **420** is used to attach the pads **3000**, **3100** to the shells **3800**, **3900**, a silicon potting compound **430** is used to secure the emitter and detector assemblies **500**, **2400** within the pads **3000**, **3100**, and a cyanoacrylic adhesive **440** secures the sensor cable **4400** to the emitter shell **3800**.

[0071] A multiple wavelength sensor has been disclosed in detail in connection with various embodiments. These embodiments are disclosed by way of examples only and are not to limit the scope of the claims that follow. One of ordinary skill in art will appreciate many variations and modifications.

Claims

1. A noninvasive physiological sensor adapted for use in an oximetry system including a monitor and a cable

communicating with said sensor, said sensor comprising:

- an electrical grid configured to activate a plurality of light emitting sources (LE710) by addressing at least one of a plurality of row conductors (720) and at least one of a plurality of column conductors (740),
a first LED (710) and a second LED (710) configured in a back-to-back arrangement so that a first contact is connected to a first LED cathode and a second LED anode and a second contact is connected to a first LED anode and a second LED cathode,
wherein the first contact is in communications with a first one of the row conductors (720) and a first one of the column conductors (740),
wherein the second contact is in communications with a second one of the row conductors (720) and a second one of the column conductors (740),
wherein the first LED is activated by addressing the first row conductor and the second column conductor, and
wherein the second LED is activated by addressing the second row conductor and the first column conductor.
2. The physiological sensor according to claim 1 further comprising an information element disposed between the first contact and the second contact.
3. The physiological sensor according to claim 2 wherein the information element is adapted to provide information in response to a DC electrical grid drive.
4. The physiological sensor according to claim 2 wherein the information element is adapted to provide information in response to an AC electrical grid drive.
5. The physiological sensor according to claim 2 wherein the information element is adapted to provide information in response to a combination of an AC electrical grid drive and a DC electrical grid drive.
6. The physiological sensor according to claim 2 wherein the information element comprises a passive information element.
7. The physiological sensor according to claim 2 wherein the information element comprises an active information element.
8. The physiological sensor according to claim 2 wherein the information element comprises a memory information element.

Patentansprüche

1. Nichtinvasiver physiologischer Sensor, der zur Verwendung in einem Oxymetriesystem mit einem Monitor und einem mit dem Sensor kommunizierenden Kabel geeignet ist, wobei der Sensor aufweist:

ein elektrisches Netz, das so konfiguriert ist, dass es mehrere Licht emittierende Quellen (LE, 710) durch Adressieren mindestens eines von mehreren Reihenleitern (720) und mindestens eines von mehreren Spaltenleitern (740) aktiviert,
eine erste LED (710) und eine zweite LED (710), die in einer Rücken-an-Rücken-Anordnung konfiguriert sind, so dass ein erster Kontakt mit einer ersten LED-Kathode und einer zweiten LED-Anode verbunden ist und ein zweiter Kontakt mit einer ersten LED-Anode und einer zweiten LED-Kathode verbunden ist,
wobei der erste Kontakt mit einem ersten der Reihenleiter (720) und einem ersten der Spaltenleiter (740) kommuniziert,
wobei der zweite Kontakt mit einem zweiten der Reihenleiter (720) und einem zweiten der Spaltenleiter (740) kommuniziert,
wobei die erste LED durch Adressieren des ersten Reihenleiters und des zweiten Spaltenleiters aktiviert wird und
wobei die zweite LED durch Adressieren des zweiten Reihenleiters und des ersten Spaltenleiters aktiviert wird.
2. Physiologischer Sensor nach Anspruch 1, ferner mit einem Informationselement, das zwischen dem ersten Kontakt und dem zweiten Kontakt angeordnet ist.
3. Physiologischer Sensor nach Anspruch 2, wobei das Informationselement geeignet ist, Informationen als Reaktion auf eine Netzansteuerung mit Gleichstrom bereitzustellen.
4. Physiologischer Sensor nach Anspruch 2, wobei das Informationselement geeignet ist, Informationen als Reaktion auf eine Netzansteuerung mit Wechselstrom bereitzustellen.
5. Physiologischer Sensor nach Anspruch 2, wobei das Informationselement geeignet ist, Informationen als Reaktion auf eine Kombination aus einer Netzansteuerung mit Wechselstrom und einer Netzansteuerung mit Gleichstrom bereitzustellen.
6. Physiologischer Sensor nach Anspruch 2, wobei das Informationselement ein passives Informationselement aufweist.
7. Physiologischer Sensor nach Anspruch 2, wobei das

Informationselement ein aktives Informationselement aufweist.

8. Physiologischer Sensor nach Anspruch 2, wobei das Informationselement ein Speicherinformationselement aufweist.

Revendications

1. Capteur physiologique non invasif adapté pour une utilisation dans un système d'oxymétrie incluant un moniteur et un câble communiquant avec ledit capteur, ledit capteur comprenant :

un réseau électrique configuré pour activer une pluralité de sources électroluminescentes (LE 710) par l'adressage d'au moins l'un d'une pluralité de conducteurs de rangée (720) et au moins l'un d'une pluralité de conducteurs de colonne (740),
une première LED (710) et une seconde LED (710) configurées dans un agencement dos-à-dos de sorte qu'un premier contact est connecté à une première cathode de LED et une seconde anode de LED et un second contact est connecté à une première anode de LED et une seconde cathode de LED,
dans lequel le premier contact est en communication avec un premier des conducteurs de rangée (720) et un premier des conducteurs de colonne (740),
dans lequel le second contact est en communication avec un second des conducteurs de rangée (720) et un second des conducteurs de colonne (740),
dans lequel la première LED est activée par adressage du premier conducteur de rangée et du second conducteur de colonne, et
dans lequel la seconde LED est activée par adressage du second conducteur de rangée et du premier conducteur de colonne.

2. Capteur physiologique selon la revendication 1, comprenant en outre un élément d'information disposé entre le premier contact et le second contact.
3. Capteur physiologique selon la revendication 2, dans lequel l'élément d'information est adapté pour fournir une information en réponse à un pilote de réseau électrique CC.
4. Capteur physiologique selon la revendication 2, dans lequel l'élément d'information est adapté pour fournir des informations en réponse à un pilote de réseau électrique CA.
5. Capteur physiologique selon la revendication 2,

dans lequel l'élément d'information est adapté pour fournir des informations en réponse à une combinaison de pilote de réseau électrique CA et un pilote de réseau électrique CC.

6. Capteur physiologique selon la revendication 2, dans lequel l'élément d'information comprend un élément d'information passif.

7. Capteur physiologique selon la revendication 2, dans lequel l'élément d'information comprend un élément d'information actif.

8. Capteur physiologique selon la revendication 2, dans lequel l'élément d'information comprend un élément d'information à mémoire.

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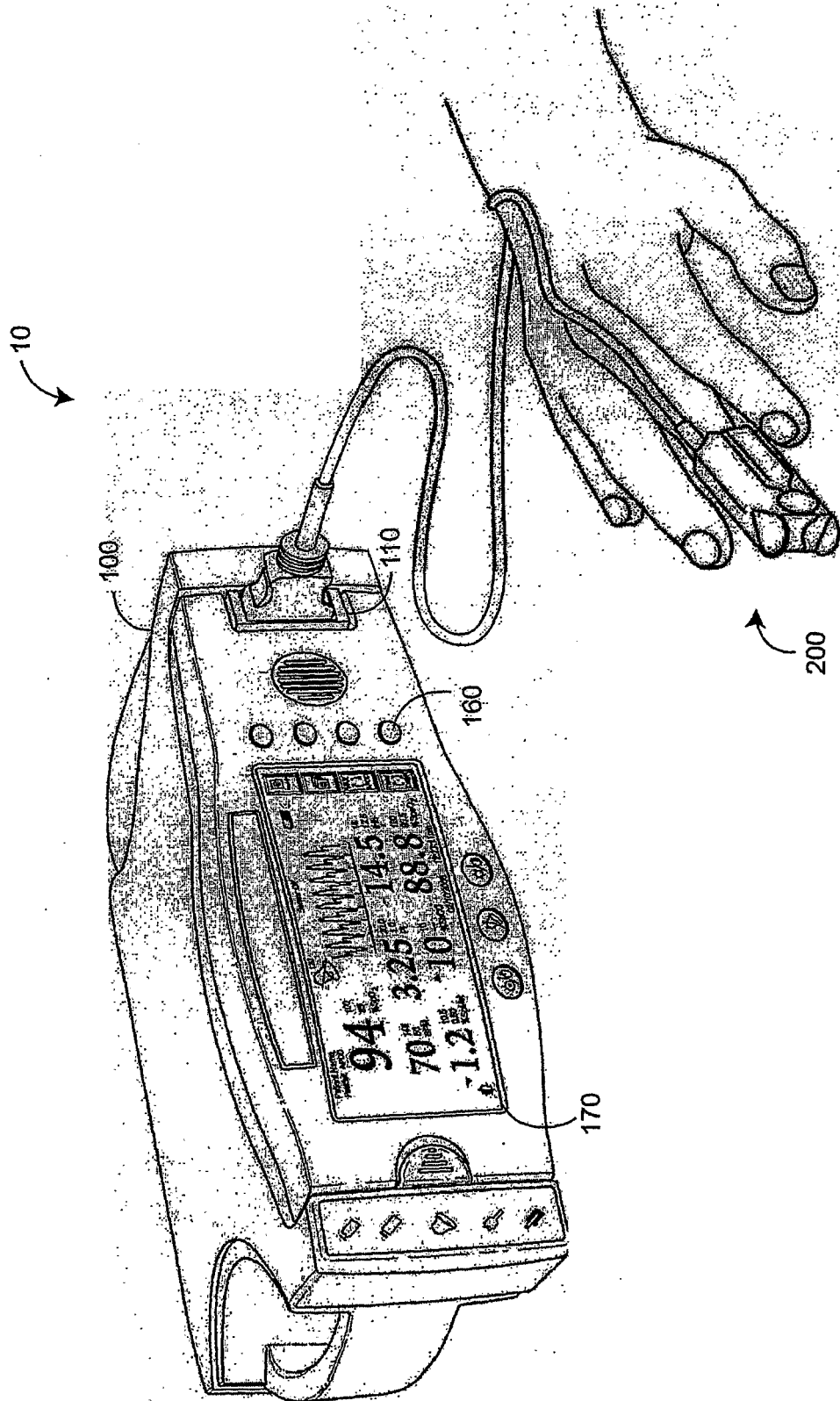


FIG. 1

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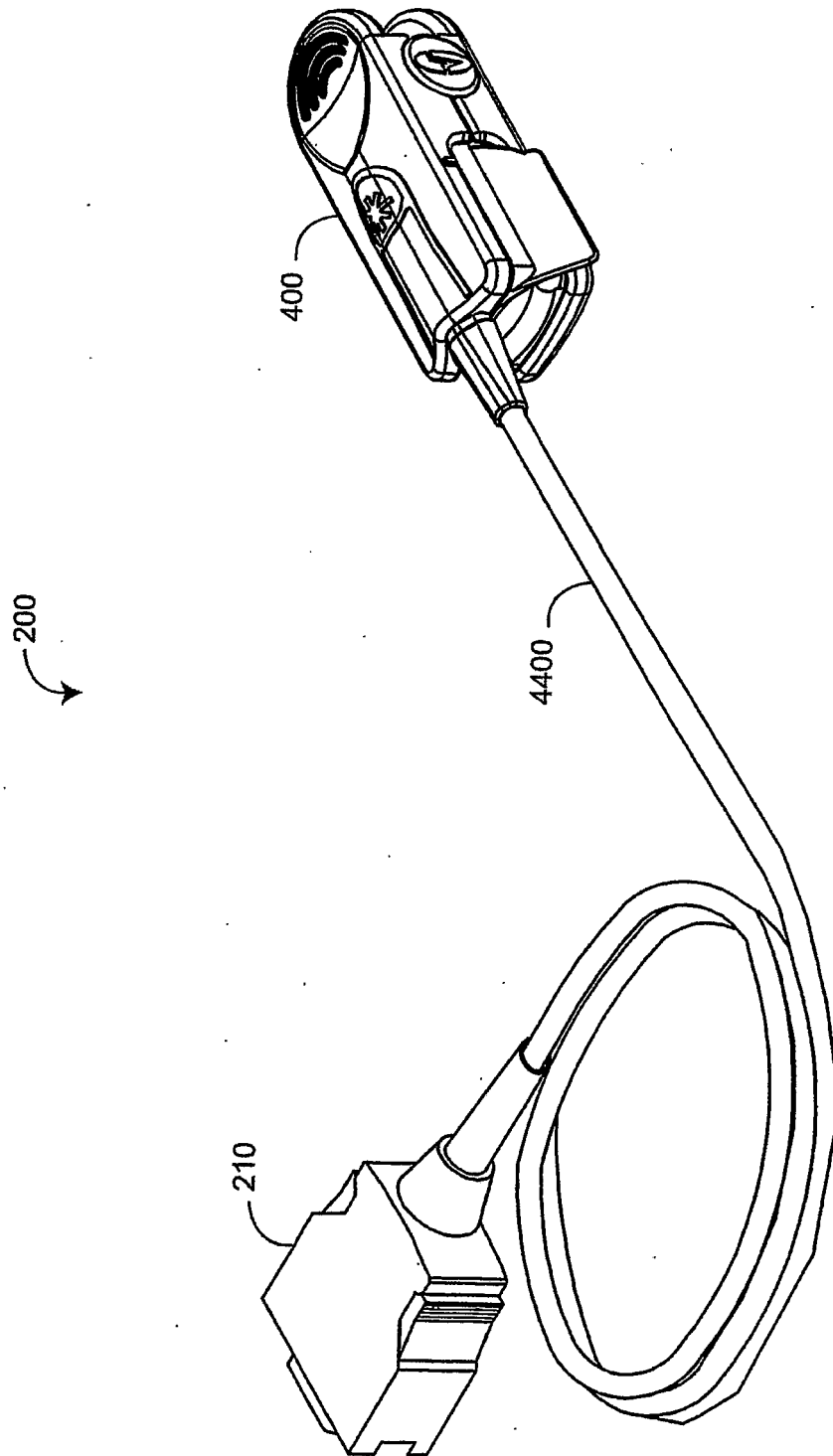


FIG. 2A

EP 2 305 104 B1

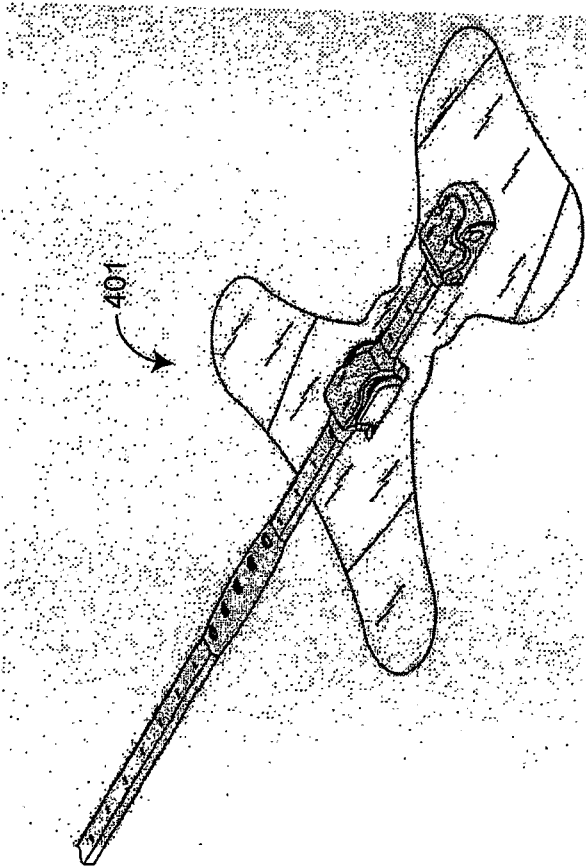


FIG. 2B

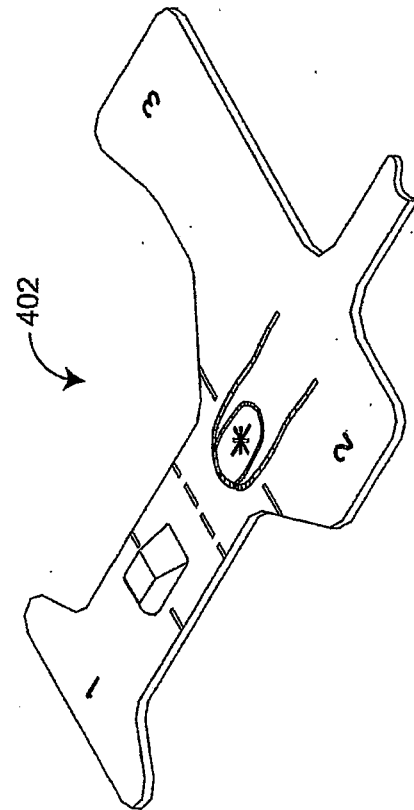


FIG. 2C

EP 2 305 104 B1

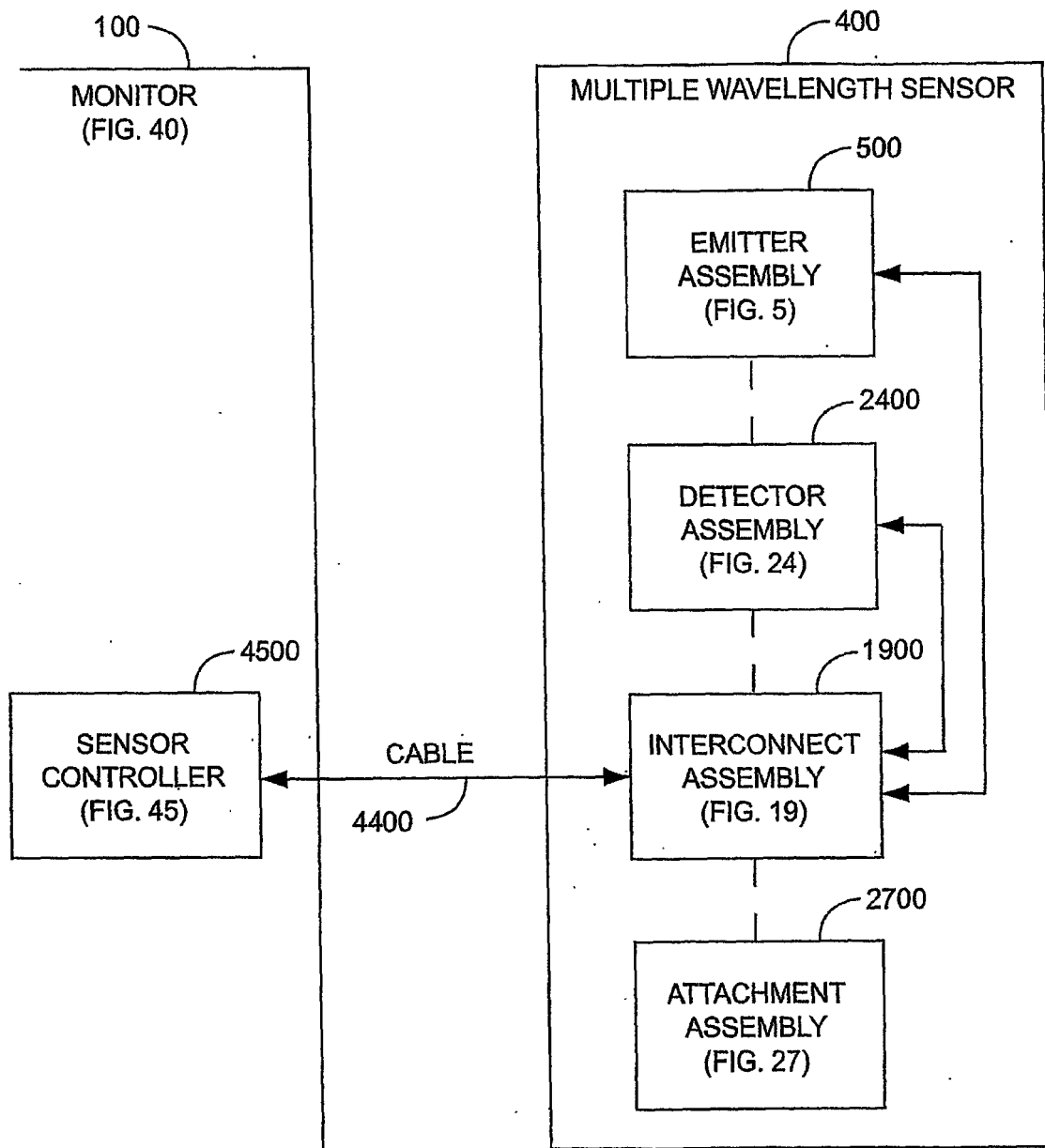


FIG. 3

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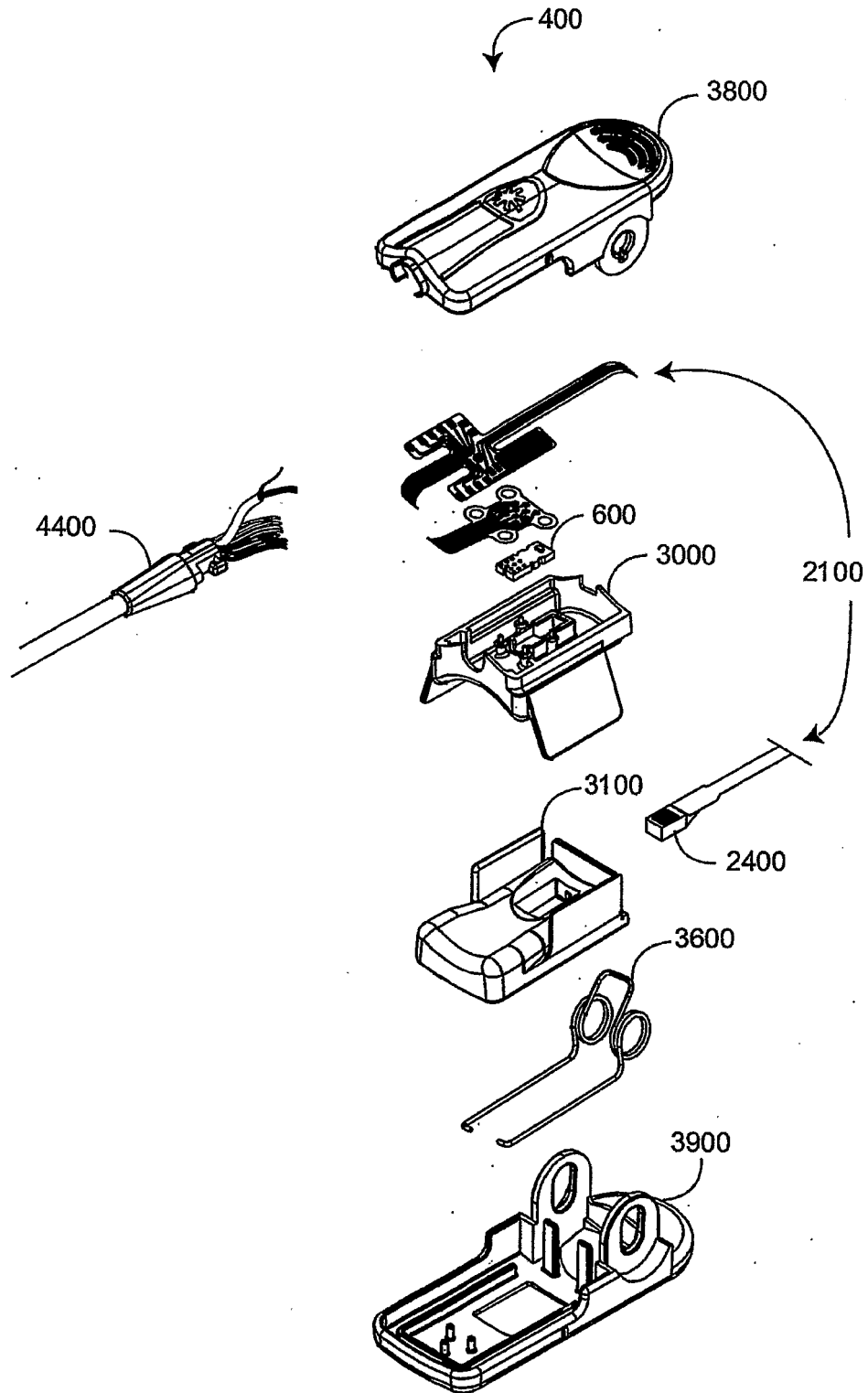


FIG. 4

EP 2 305 104 B1

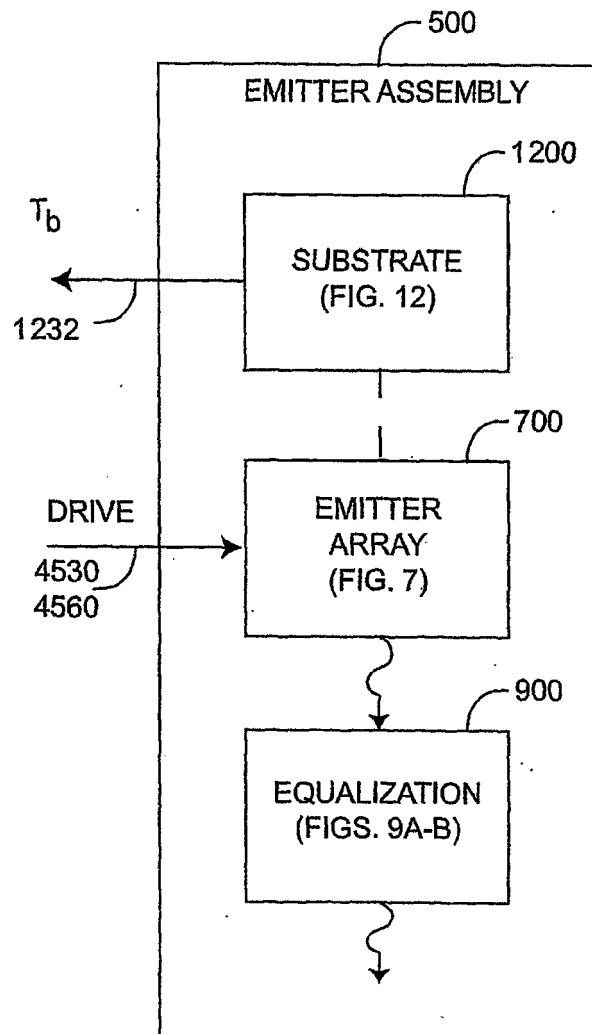


FIG. 5

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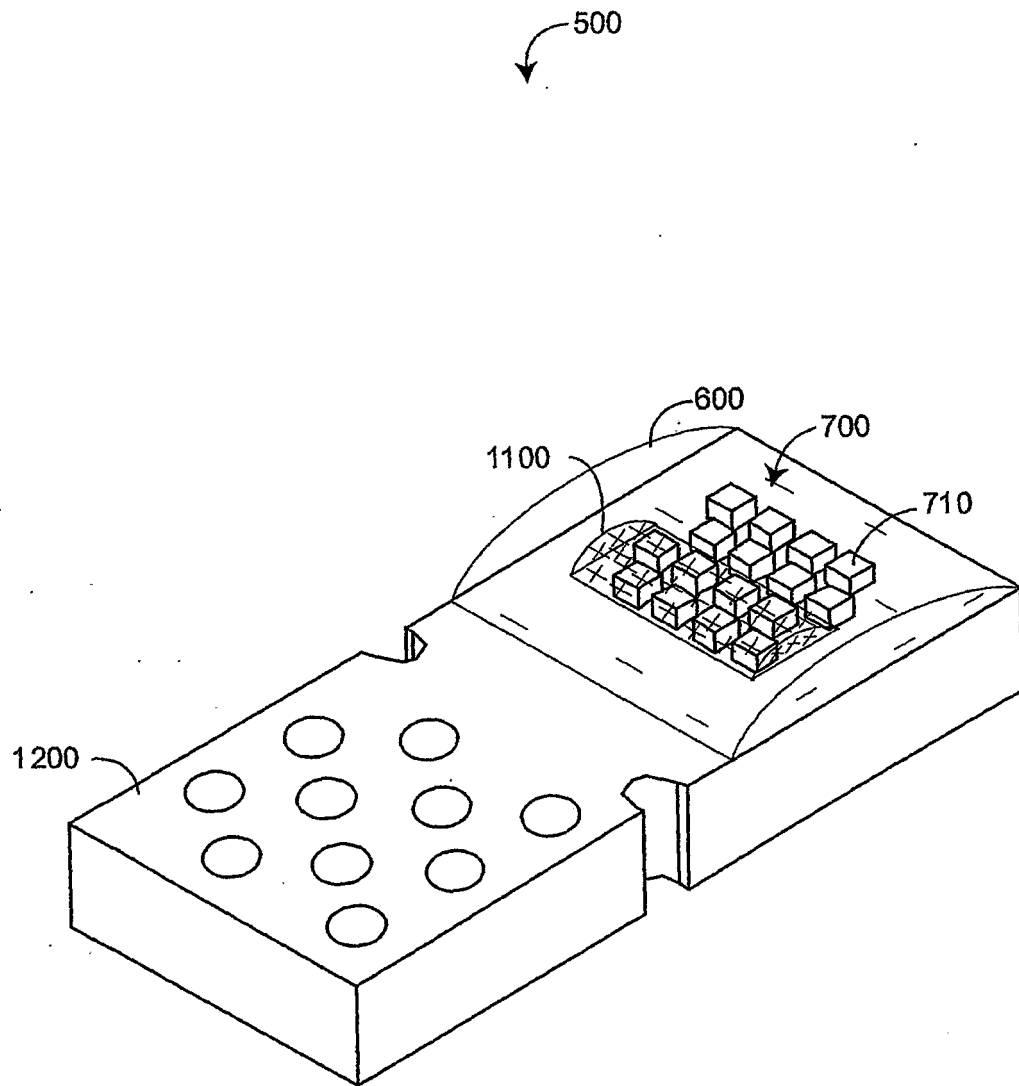


FIG. 6

EP 2 305 104 B1

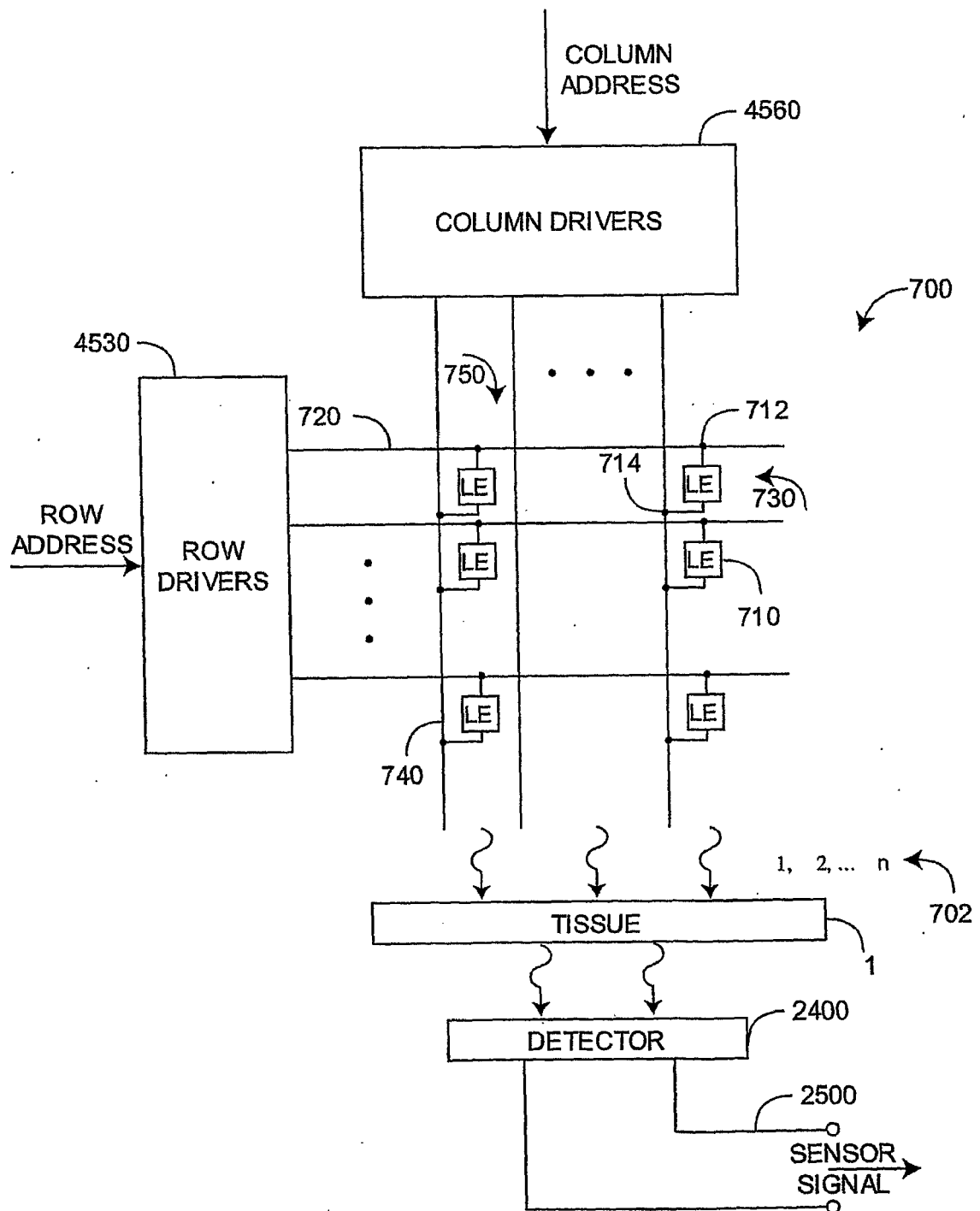


FIG. 7

EP 2 305 104 B1

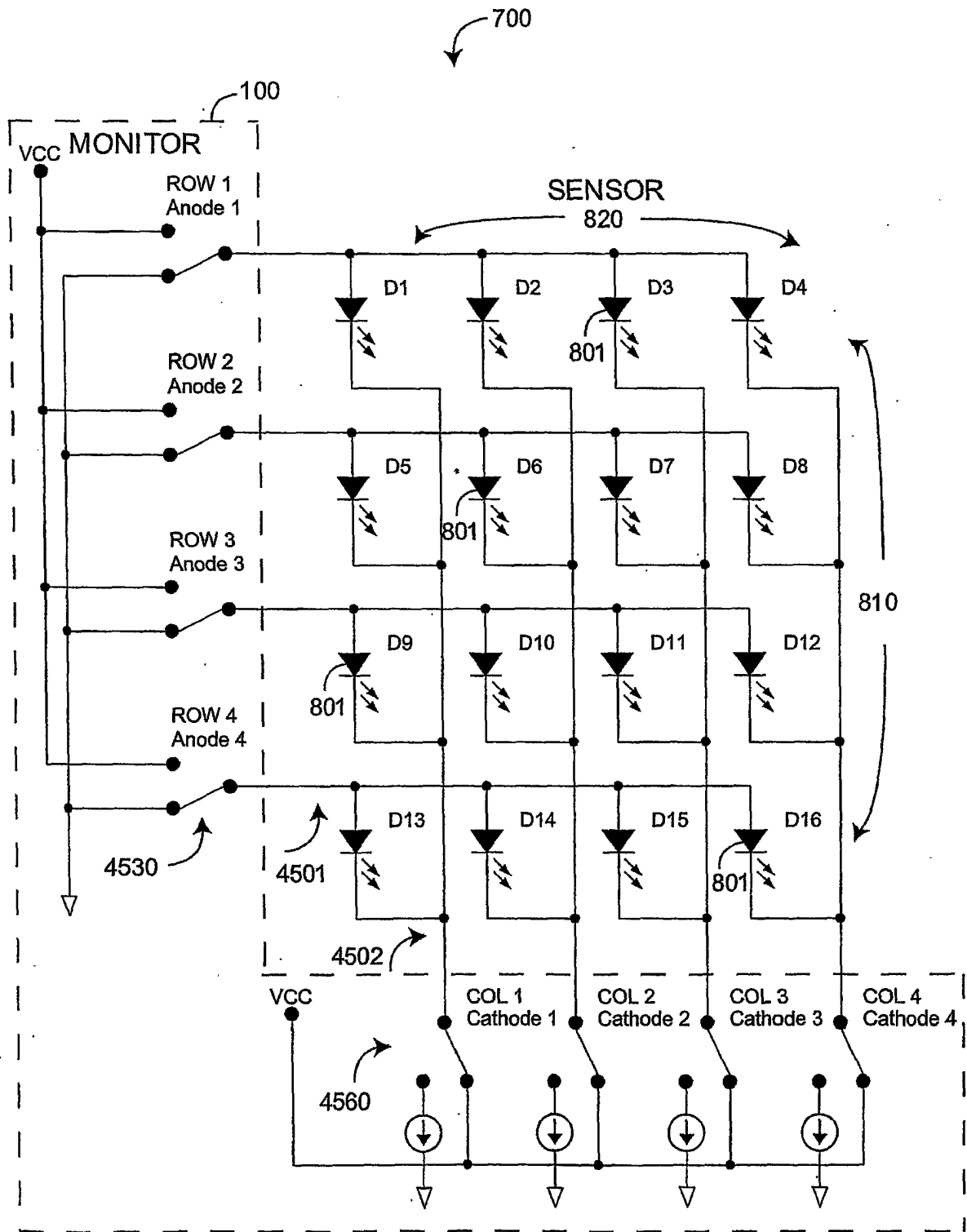


FIG. 8

EP 2 305 104 B1

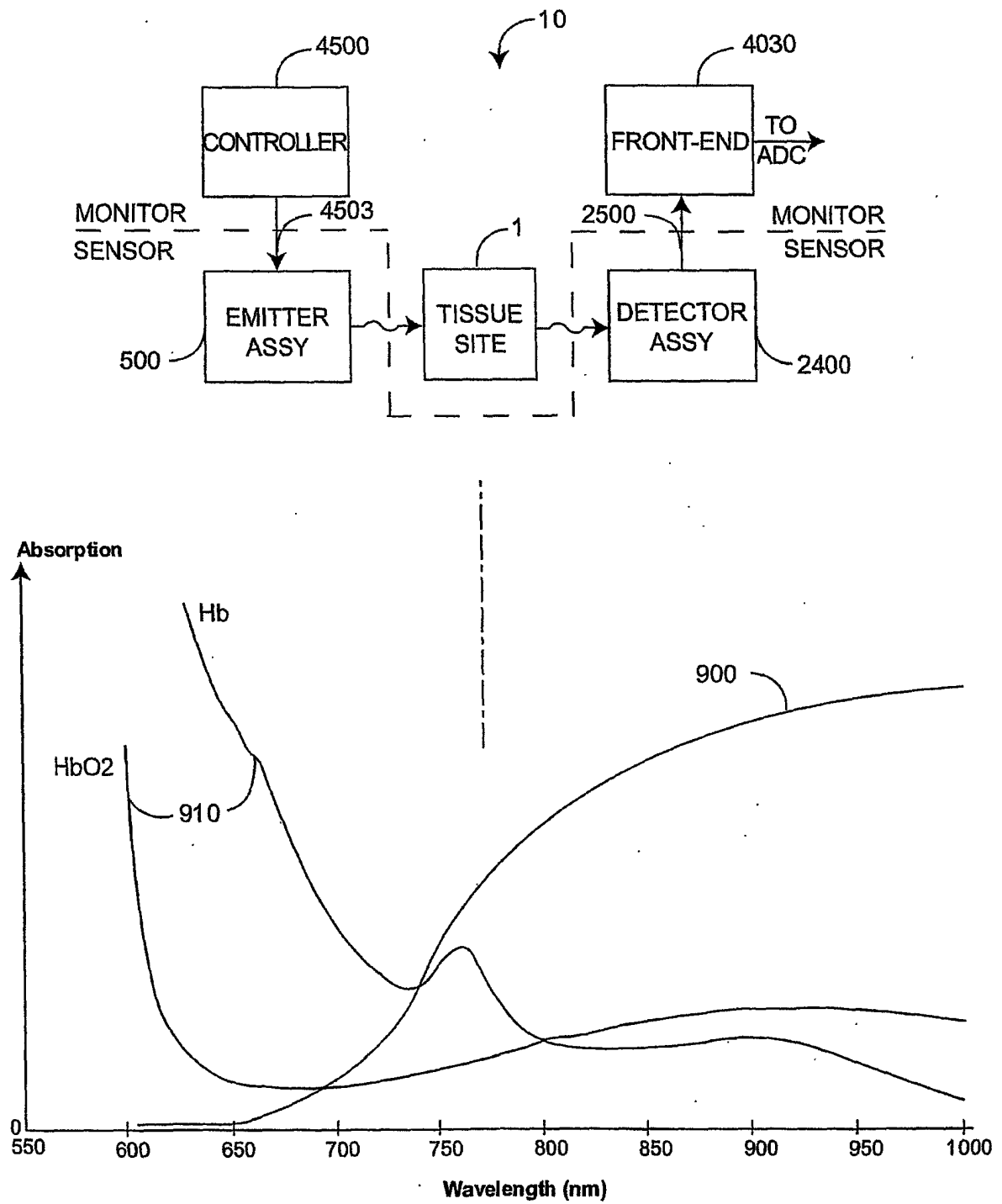


FIG. 9

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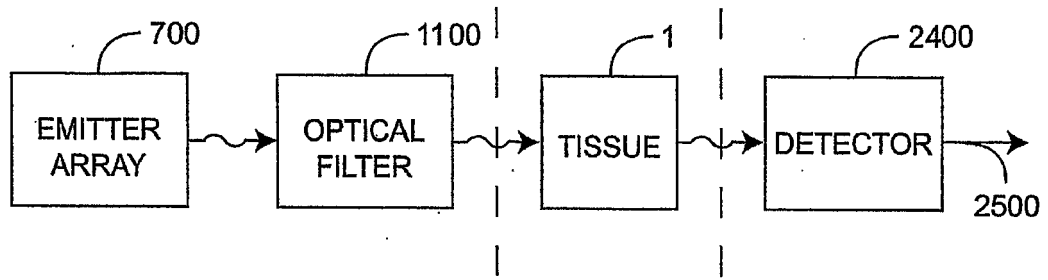


FIG. 10A

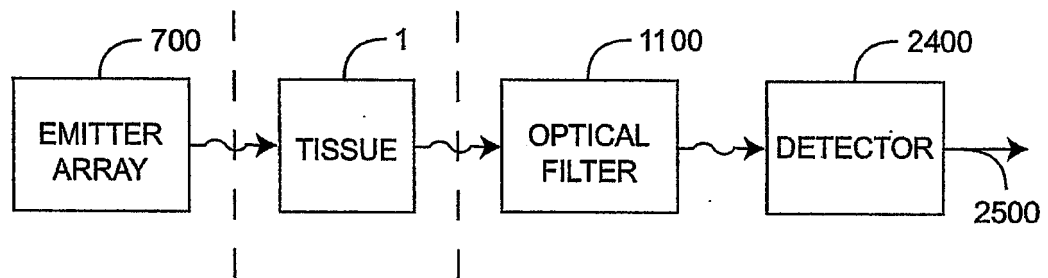


FIG. 10B

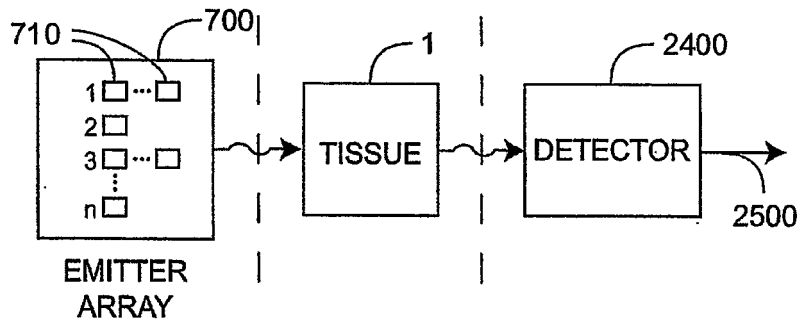


FIG. 10C

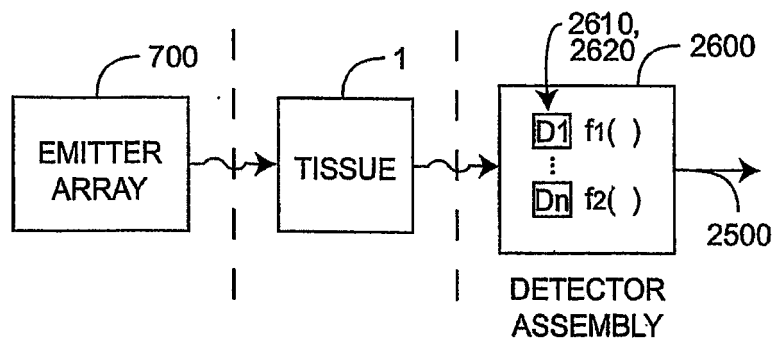


FIG. 10D

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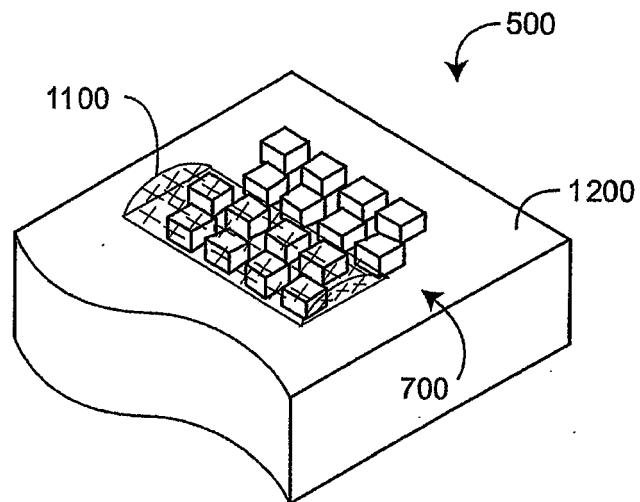


FIG. 11A

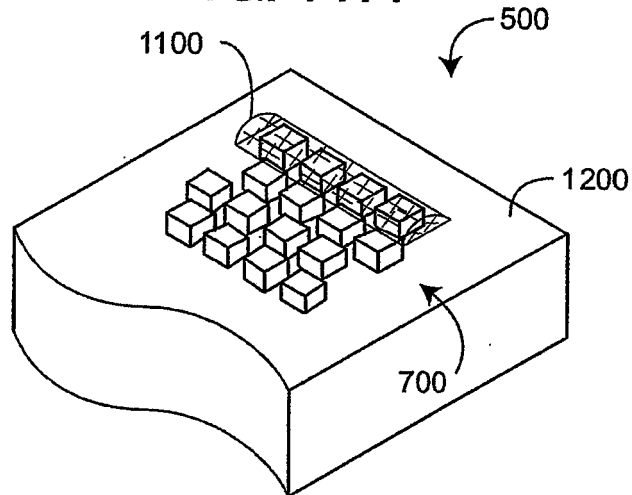


FIG. 11B

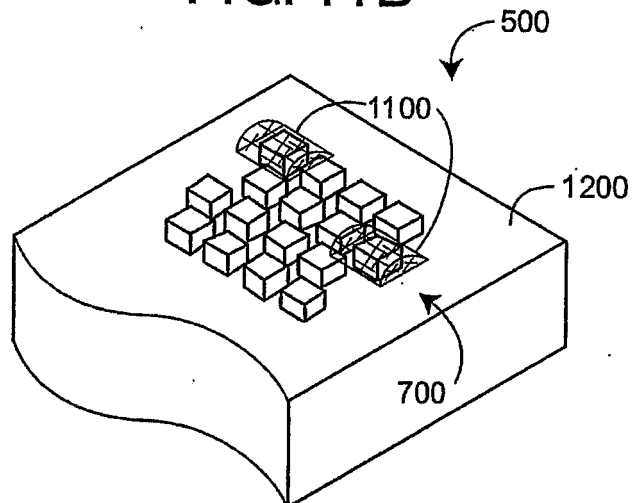


FIG. 11C

EP 2 305 104 B1

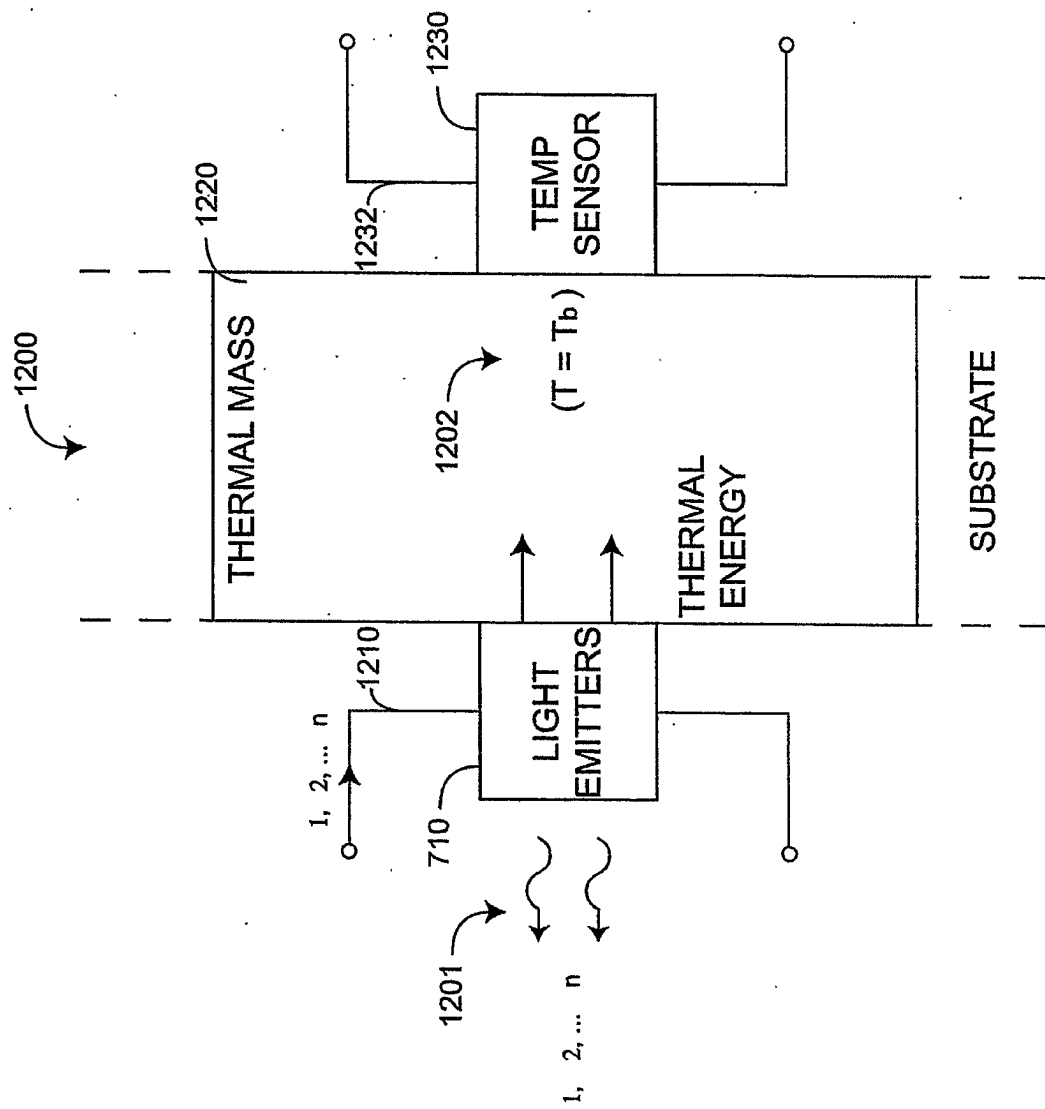
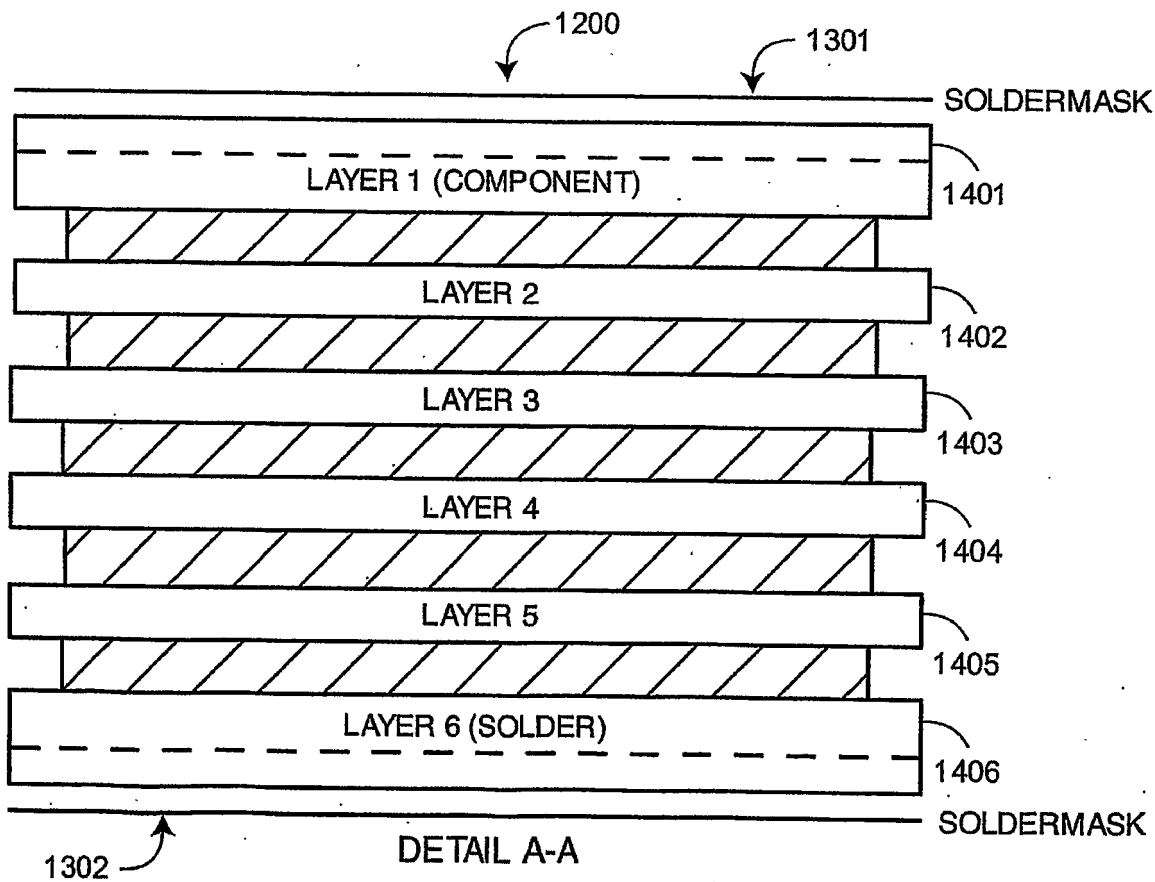
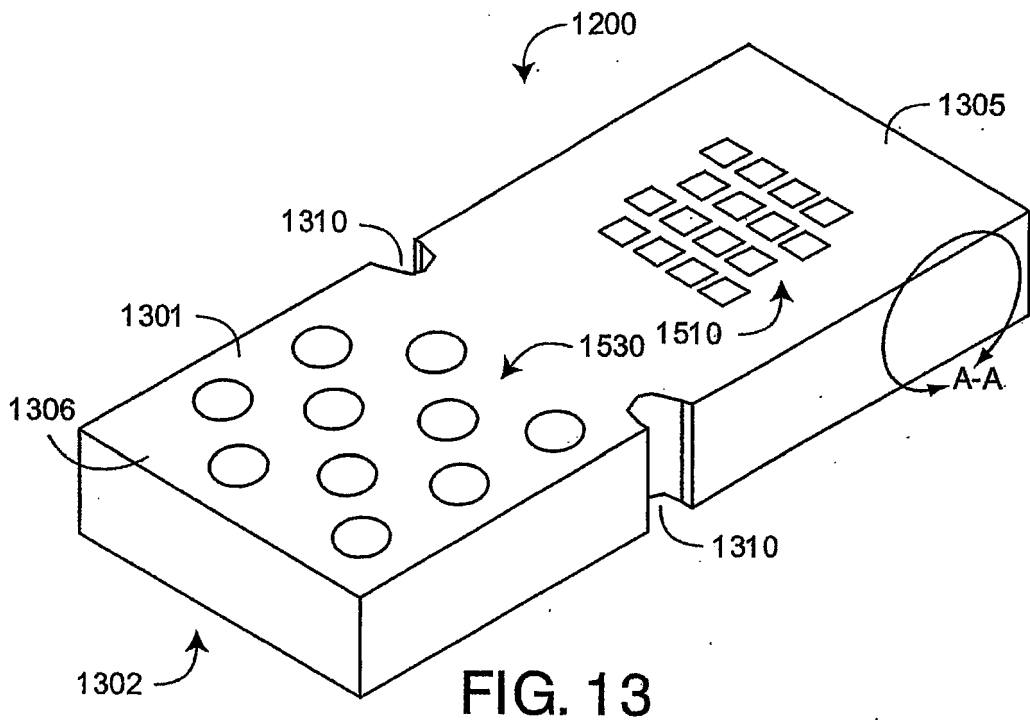


FIG. 12

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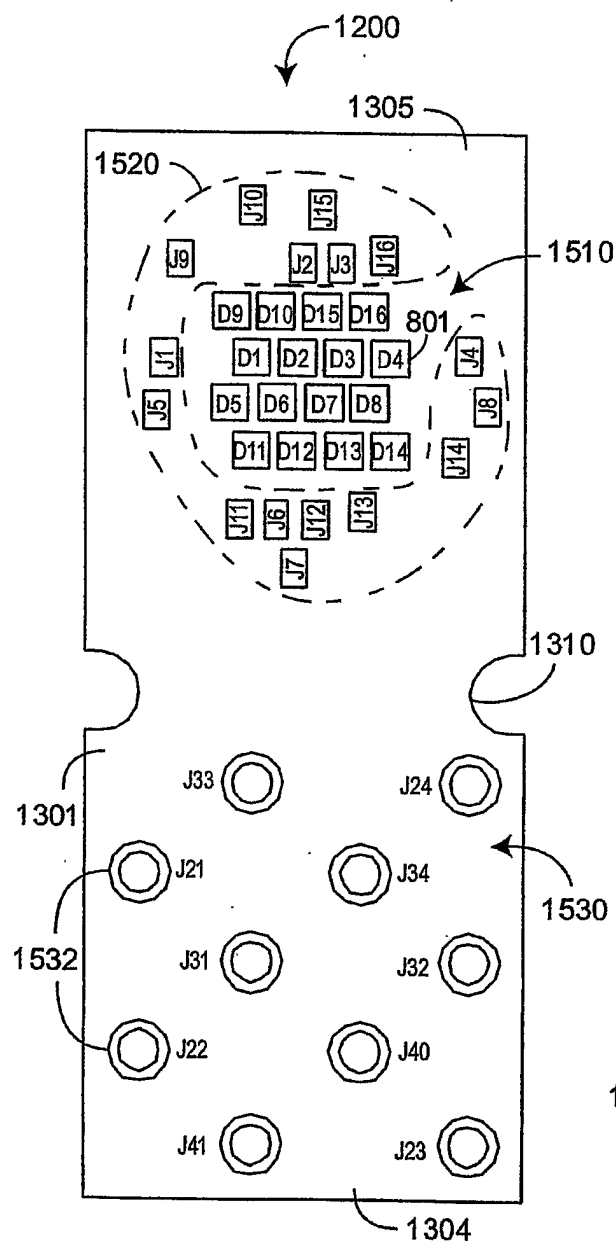


FIG. 15

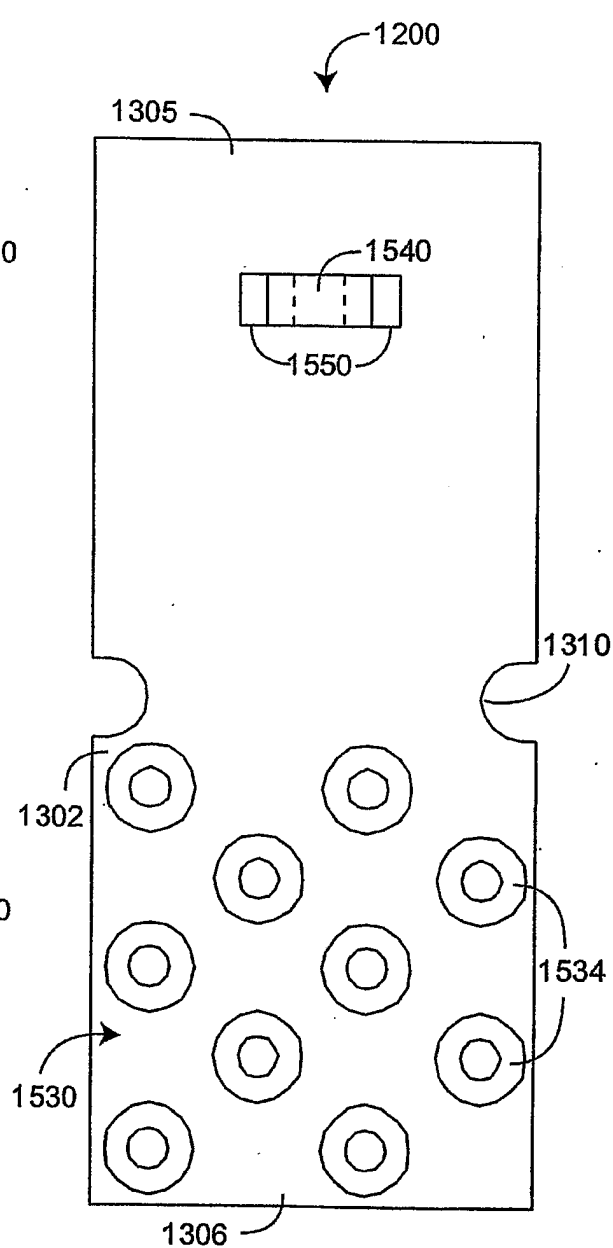


FIG. 16

EP 2 305 104 B1

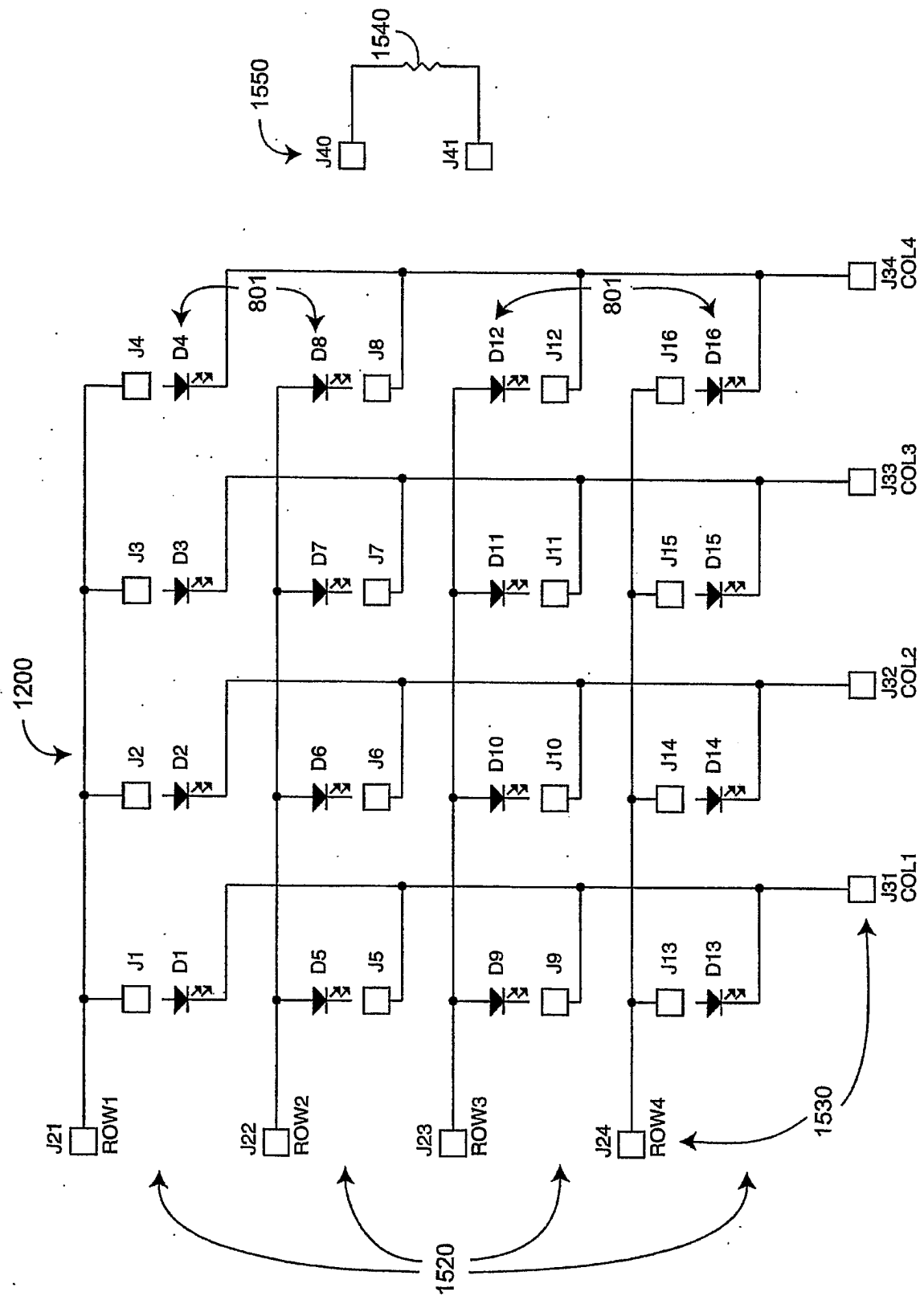
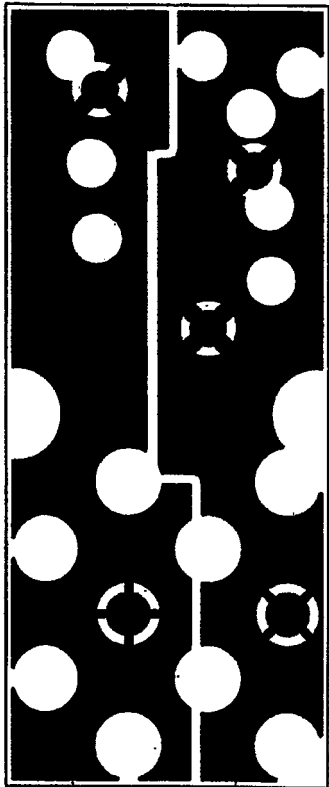


FIG. 17

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1402



1411

FIG. 18

EP 2 305 104 B1

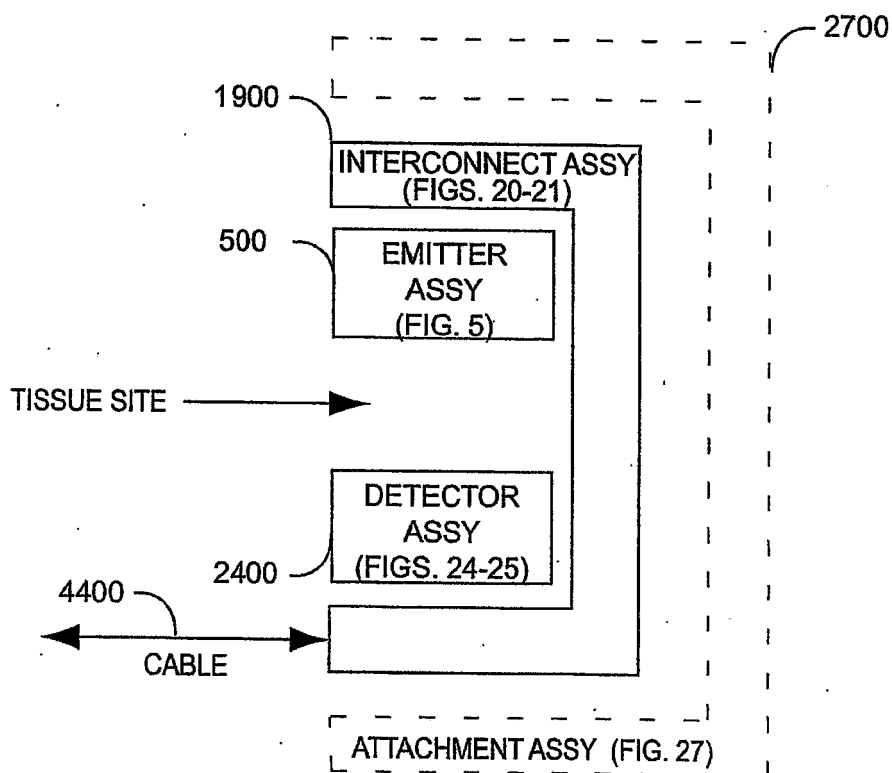


FIG. 19

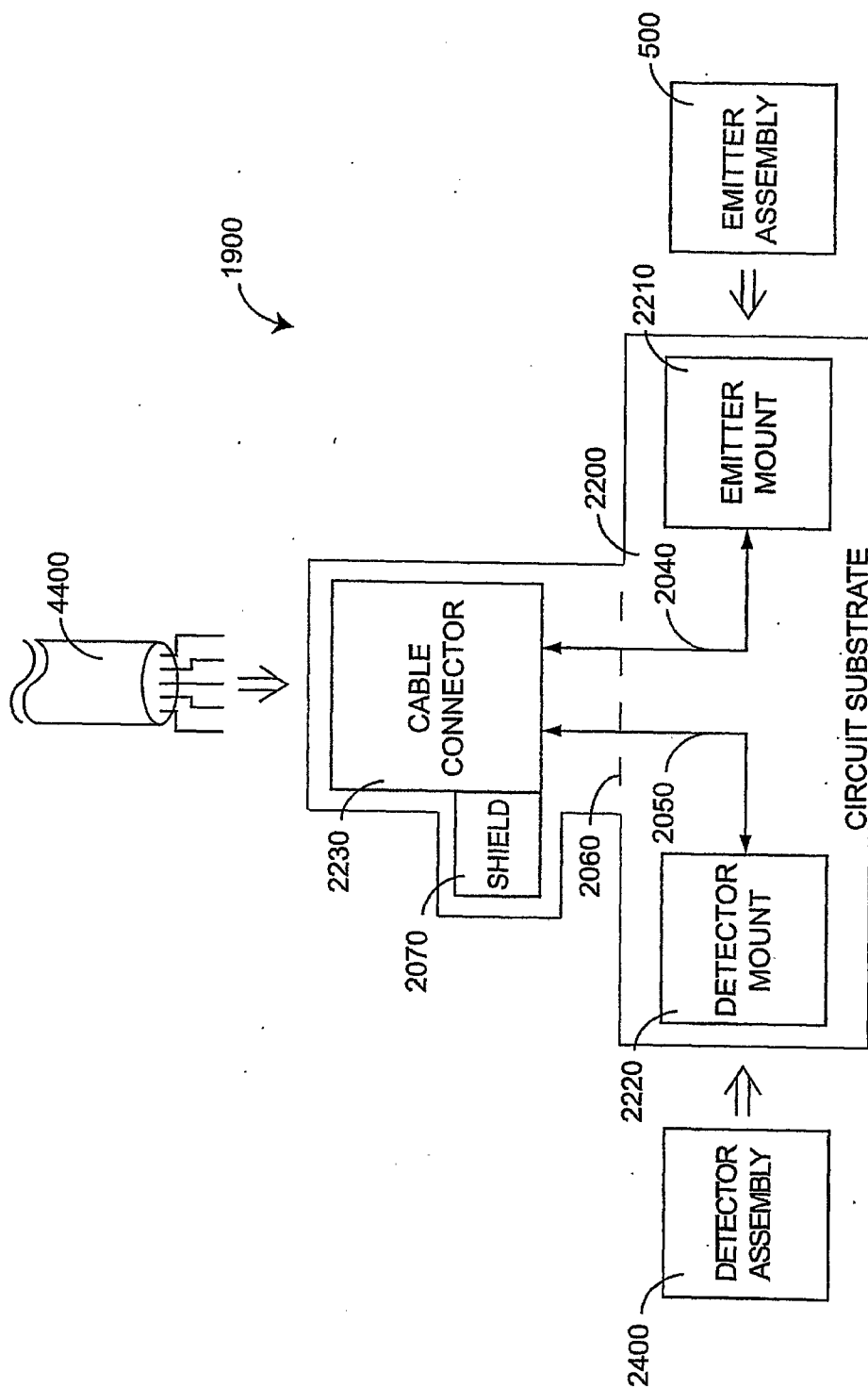


FIG. 20

EP 2 305 104 B1

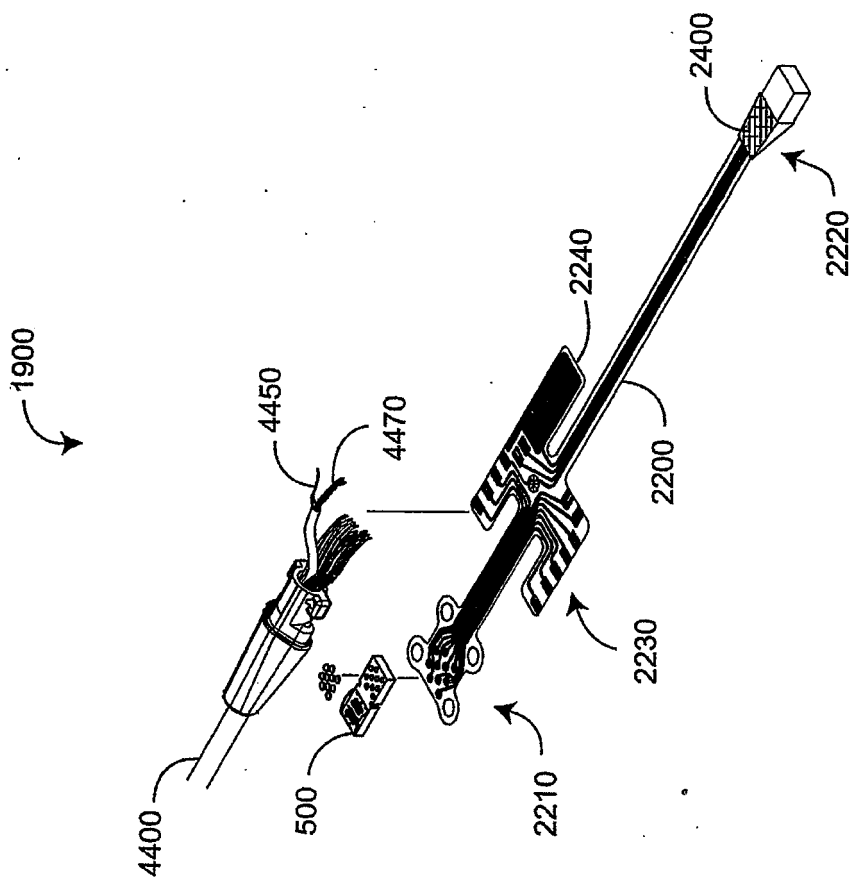


FIG. 21

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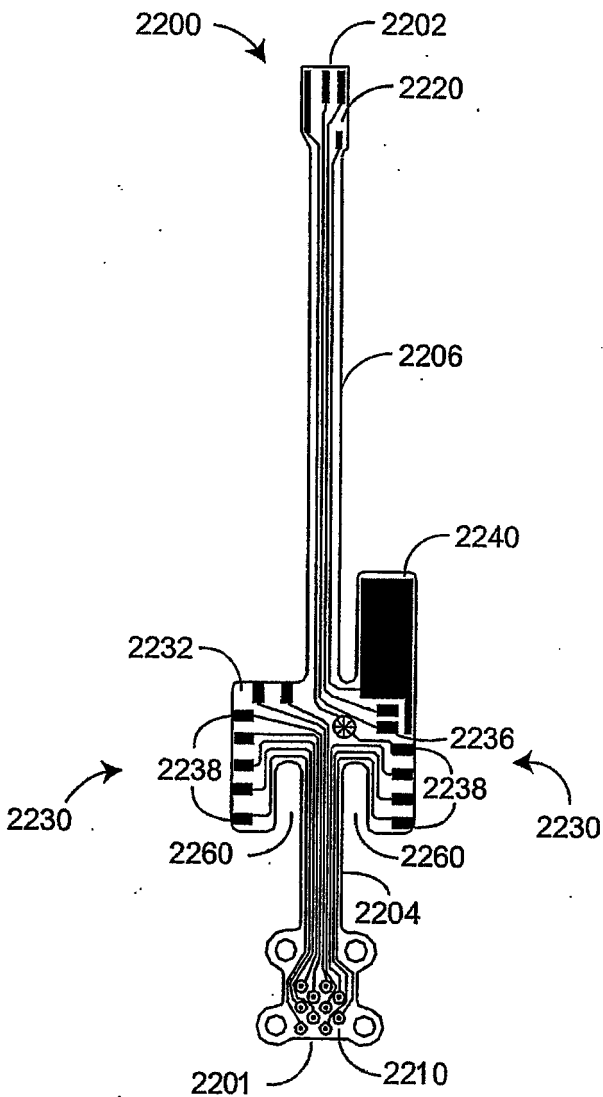


FIG. 22

EP 2 305 104 B1

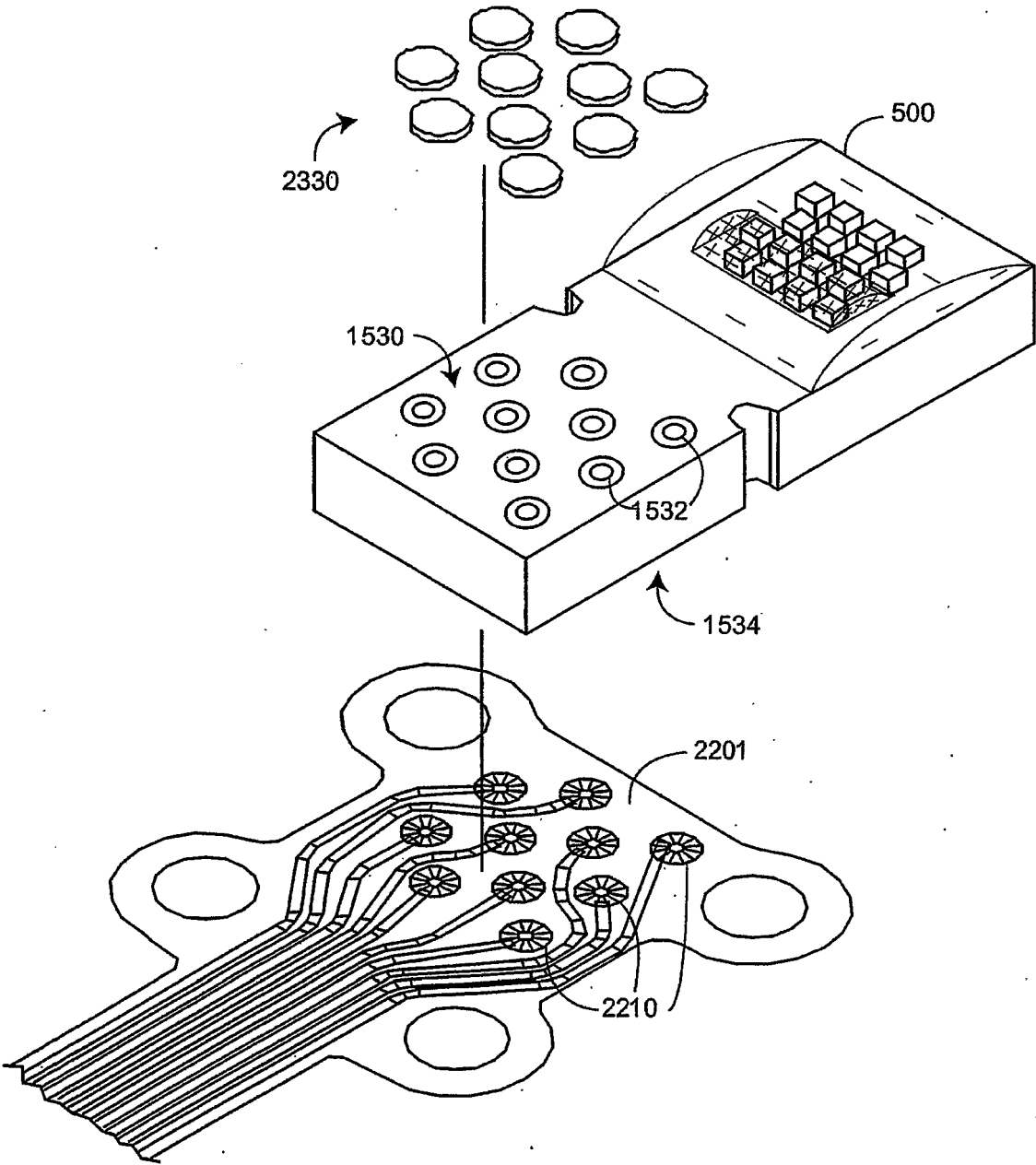


FIG. 23

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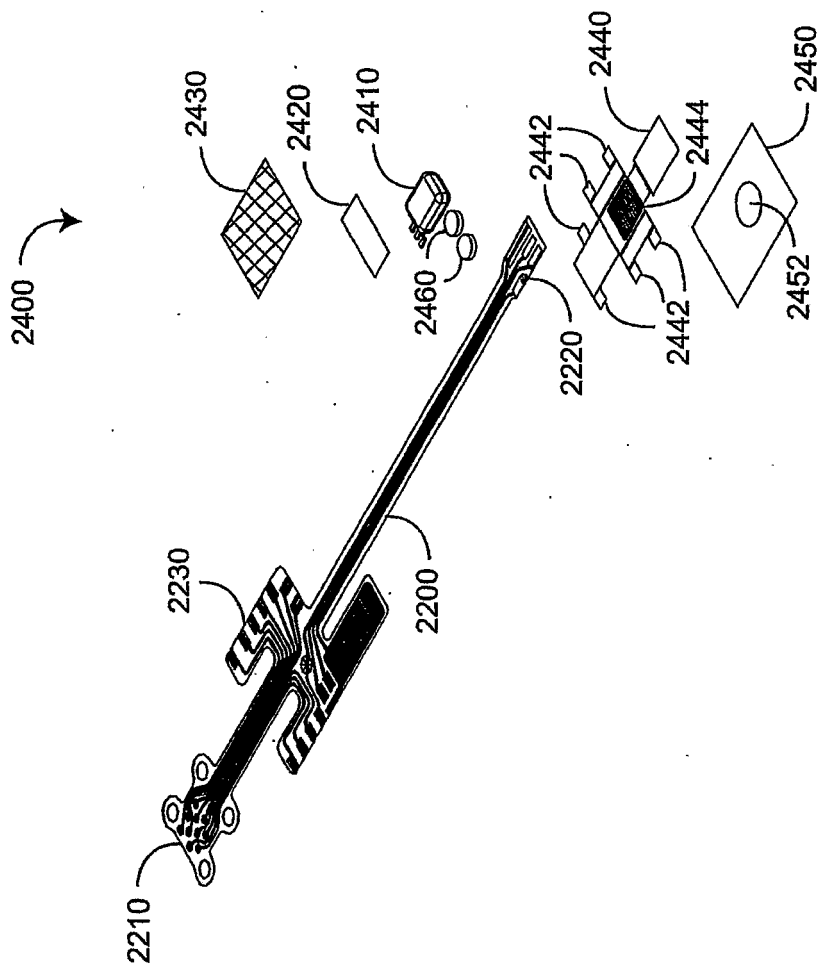


FIG. 24

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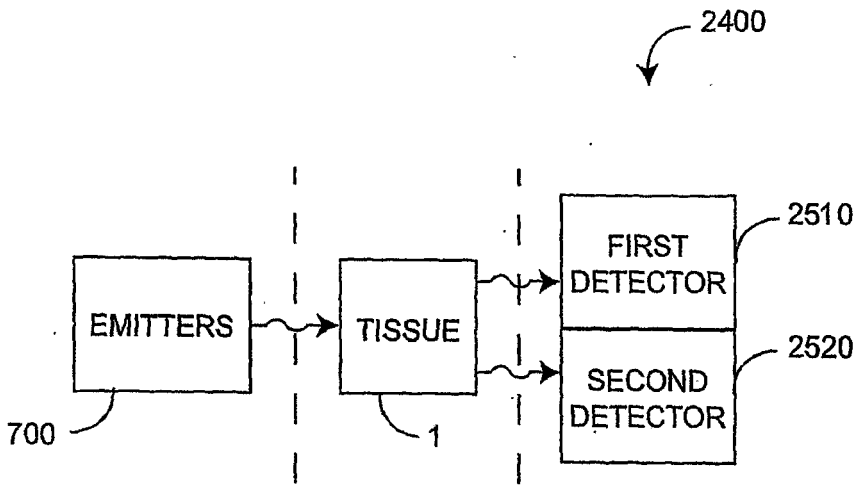


FIG. 25

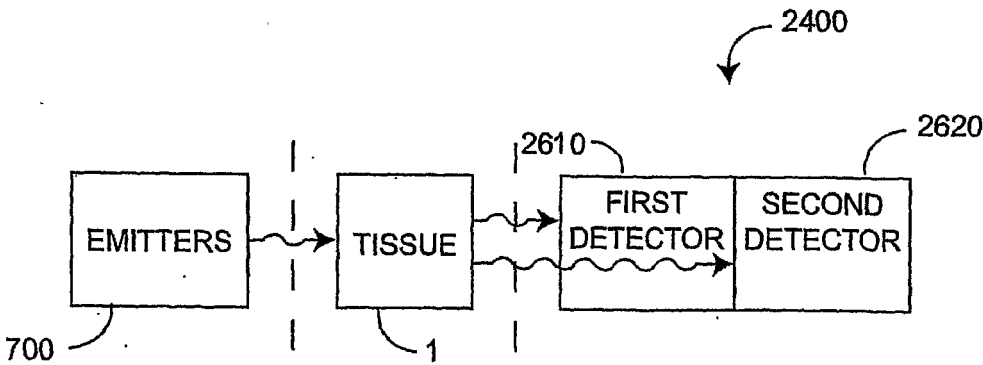


FIG. 26

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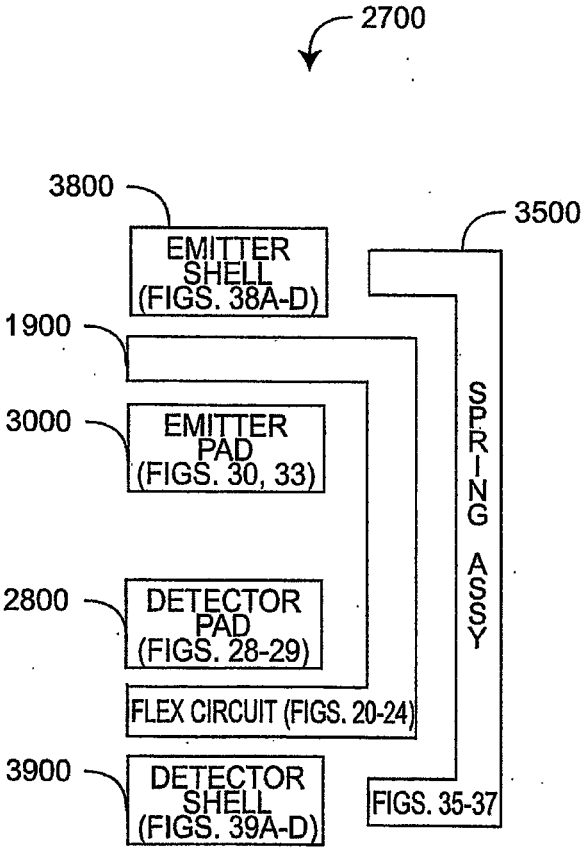


FIG. 27

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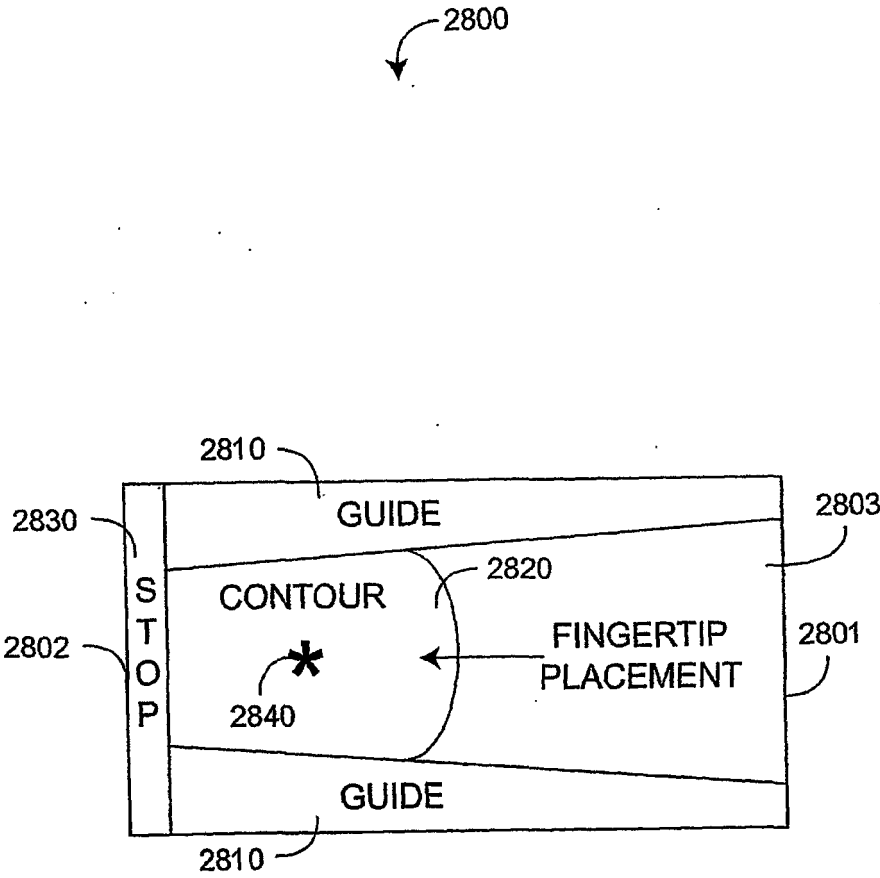


FIG. 28

EP 2 305 104 B1

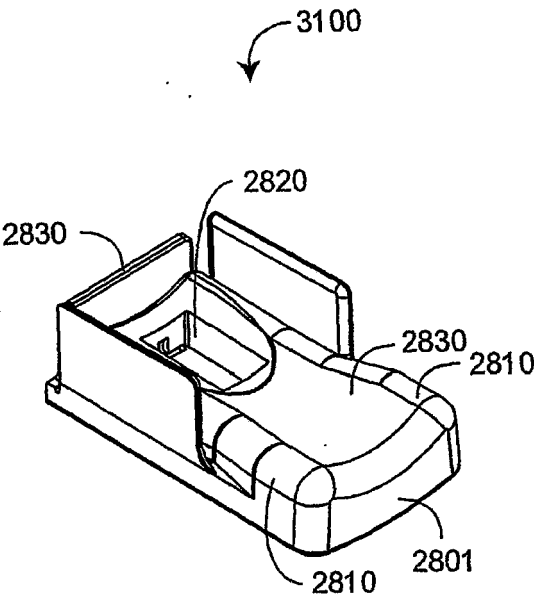


FIG. 29A

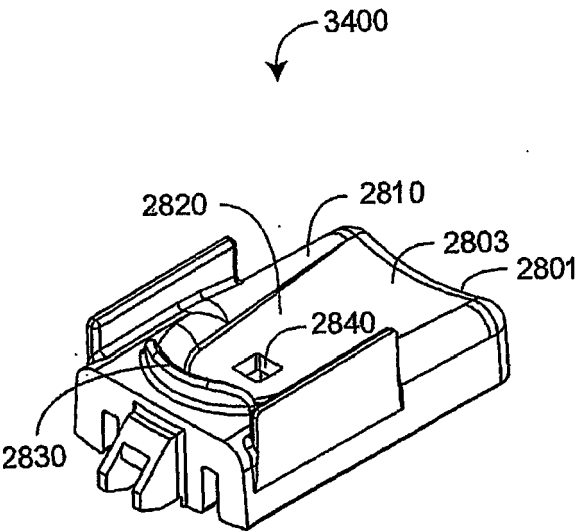


FIG. 29B

EP 2 305 104 B1

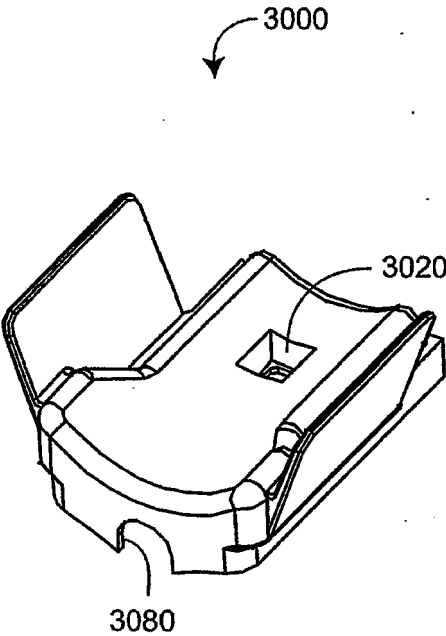


FIG. 30A

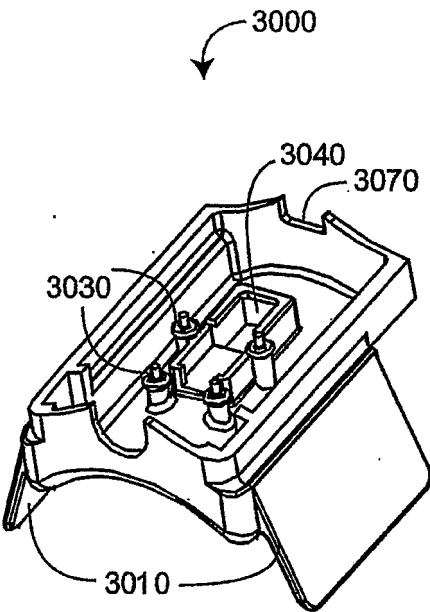


FIG. 30B

EP 2 305 104 B1

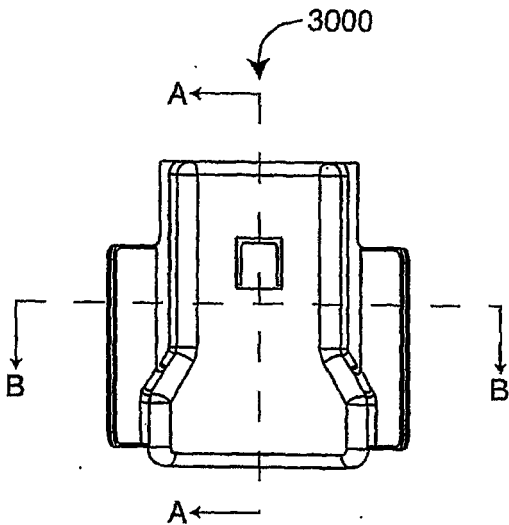
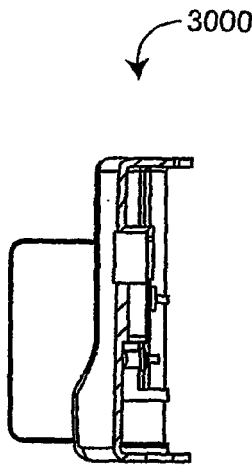


FIG. 30C



SECTION A-A
FIG. 30F

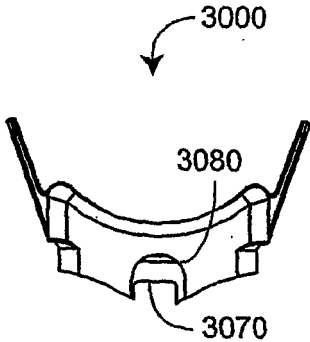


FIG. 30D

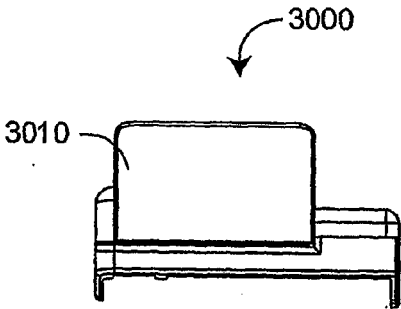


FIG. 30G

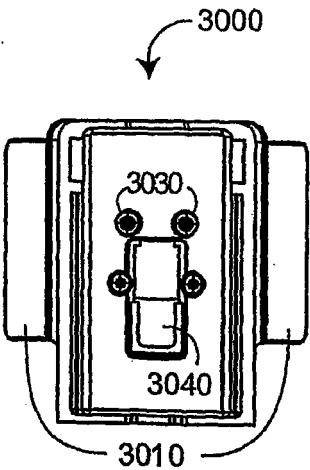
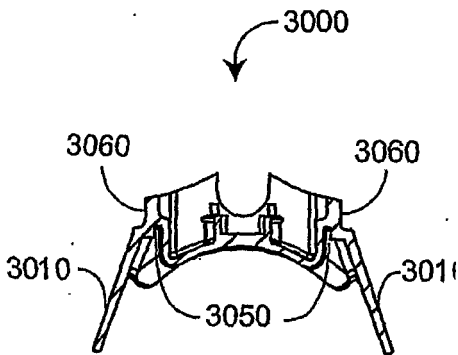


FIG. 30E



SECTION B-B

FIG. 30H

EP 2 305 104 B1

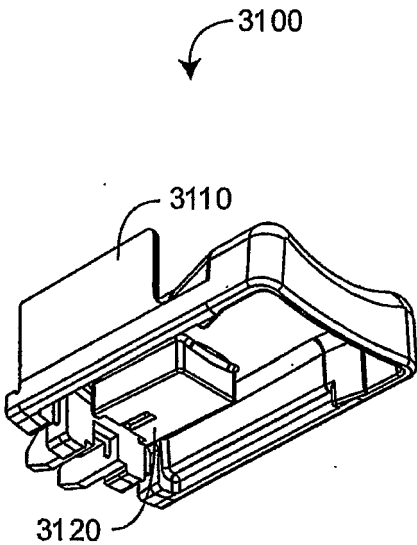


FIG. 31A

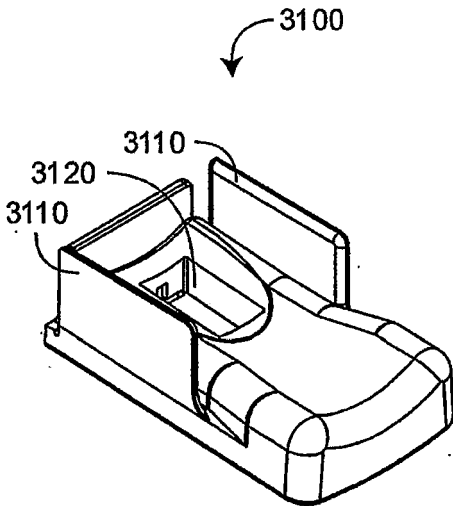


FIG. 31B

EP 2 305 104 B1

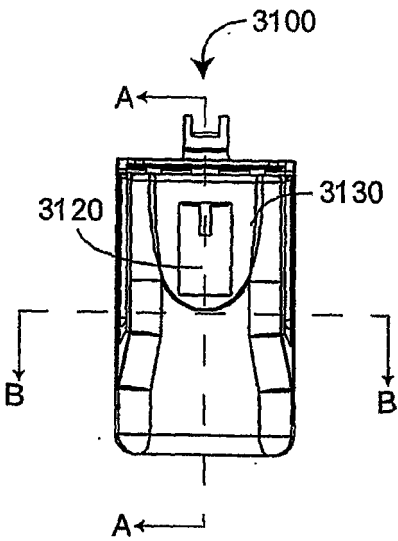
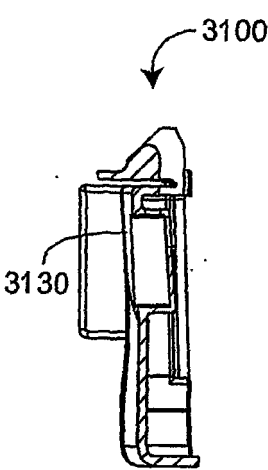


FIG. 31C



SECTION A-A

FIG. 31F

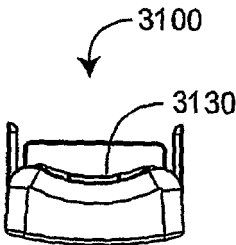


FIG. 31D

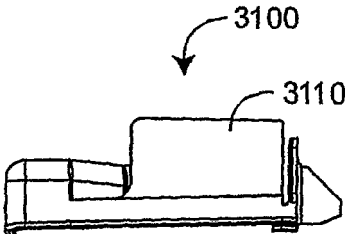


FIG. 31G

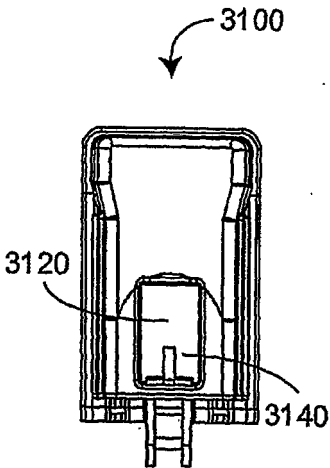
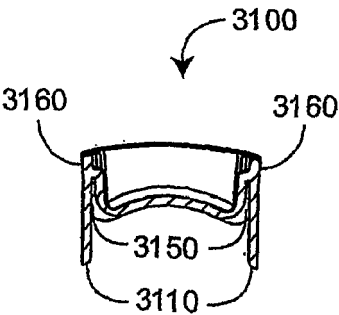


FIG. 31E



SECTION B-B

FIG. 31H

EP 2 305 104 B1

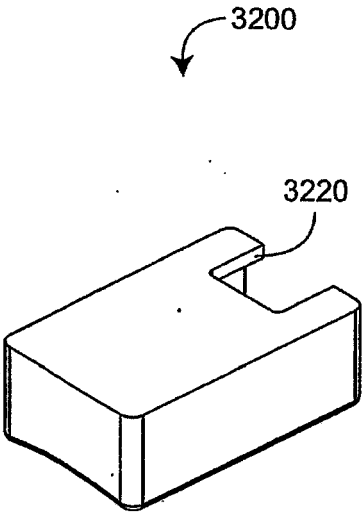


FIG. 32A

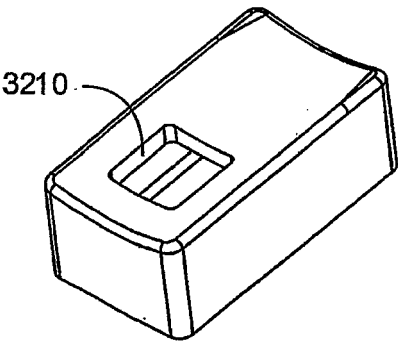


FIG. 32B

EP 2 305 104 B1

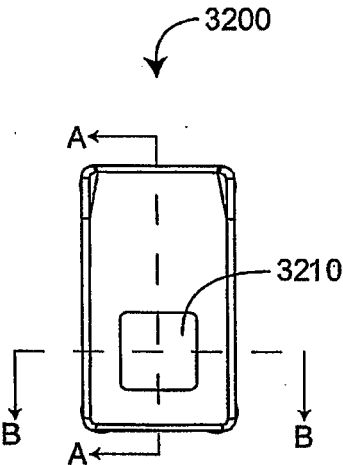
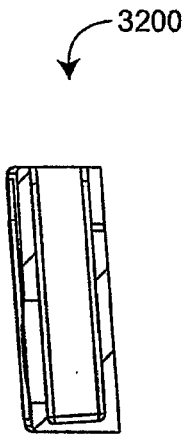


FIG. 32C



SECTION A-A

FIG. 32F

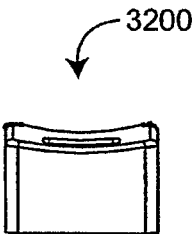


FIG. 32D

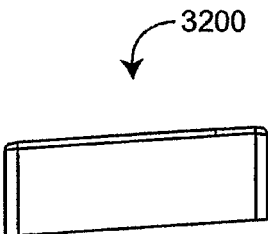


FIG. 32G

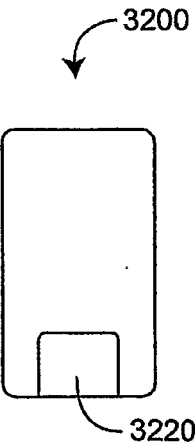
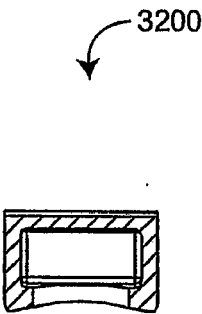


FIG. 32E



SECTION B-B

FIG. 32H

EP 2 305 104 B1

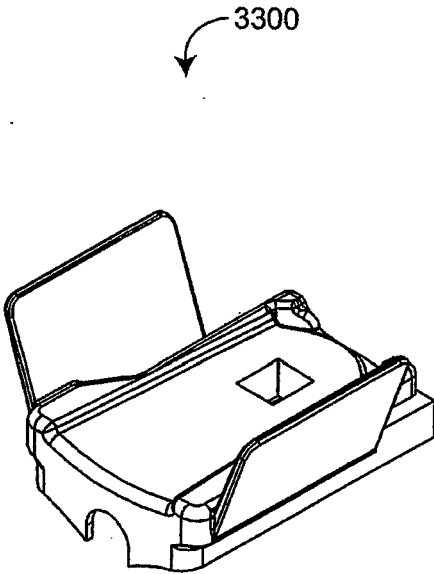


FIG. 33A

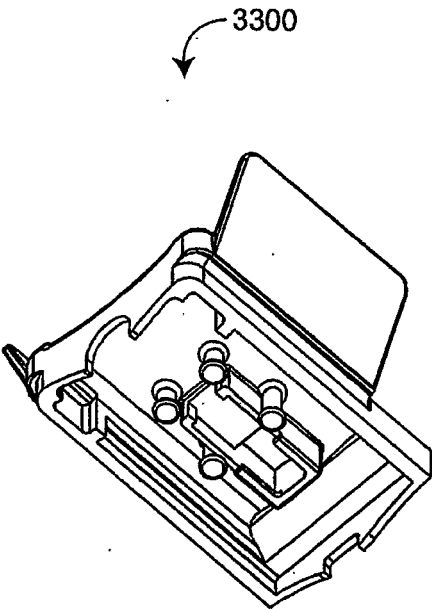


FIG. 33B

EP 2 305 104 B1

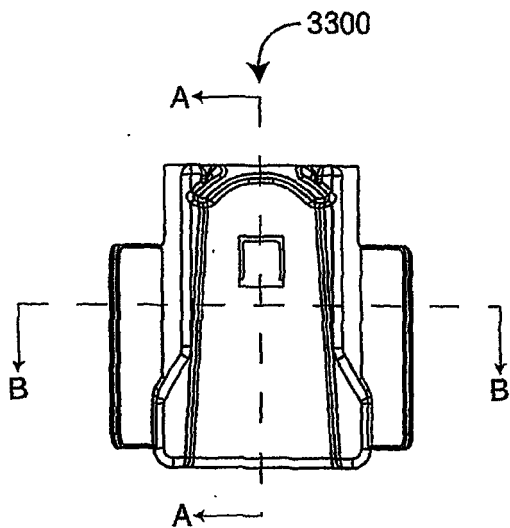
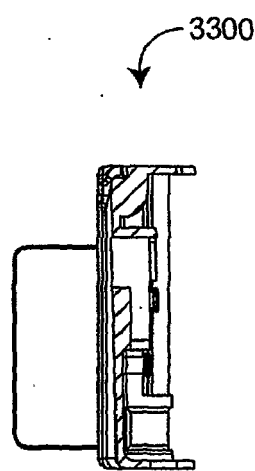


FIG. 33C



SECTION A-A
FIG. 33F

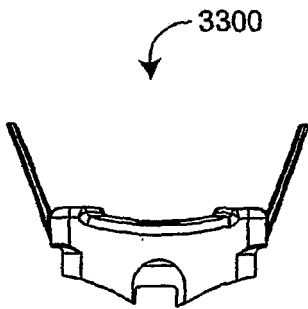


FIG. 33D

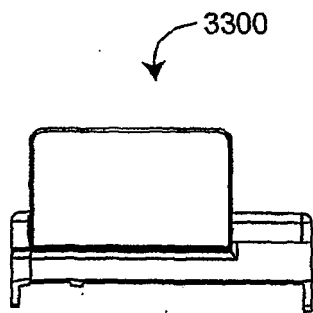


FIG. 33G

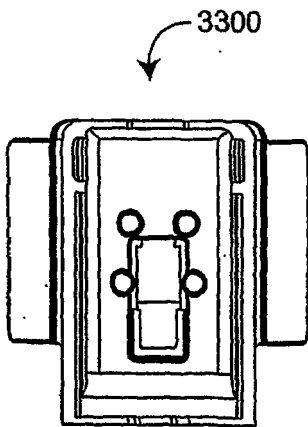
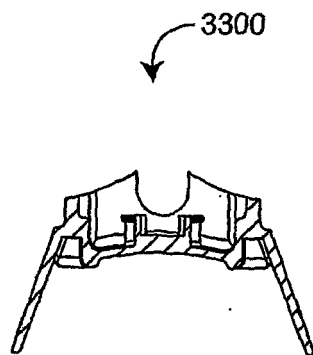


FIG. 33E



SECTION B-B
FIG. 33H

EP 2 305 104 B1

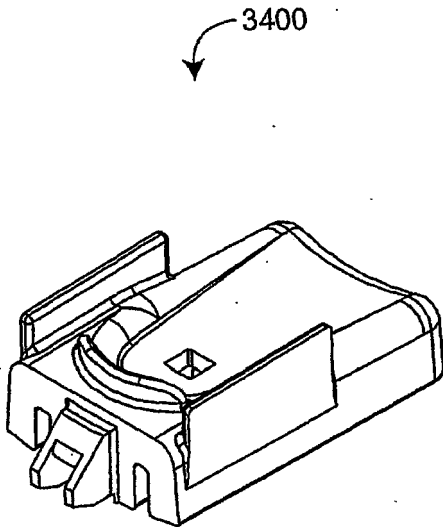


FIG. 34A

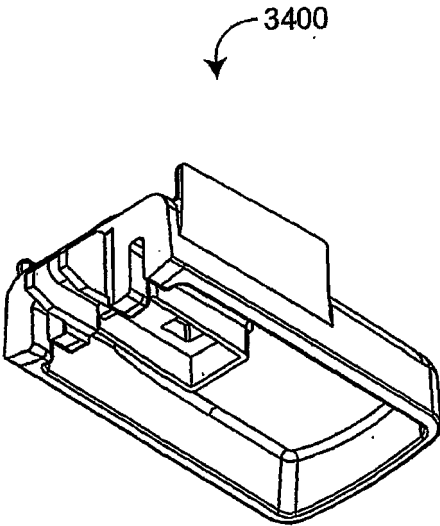


FIG. 34B

EP 2 305 104 B1

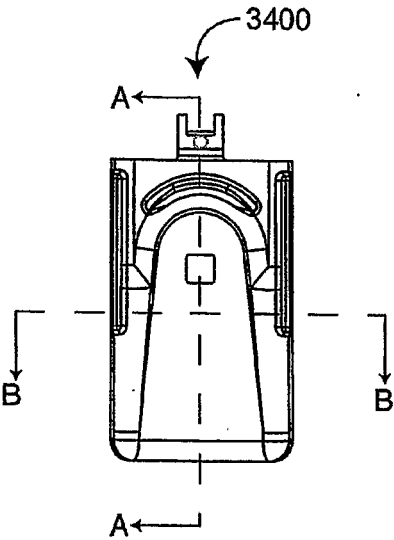
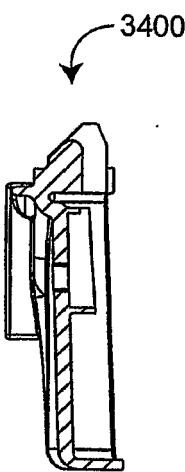


FIG. 34C



SECTION A-A

FIG. 34F

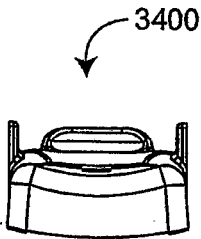


FIG. 34D

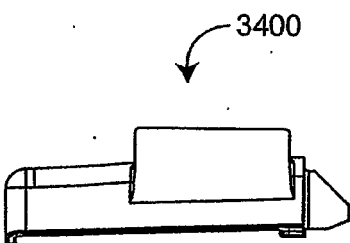


FIG. 34G

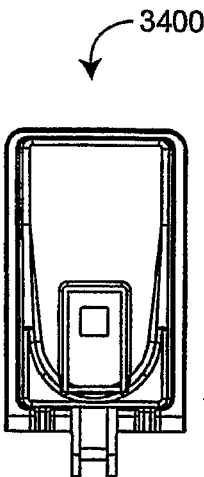
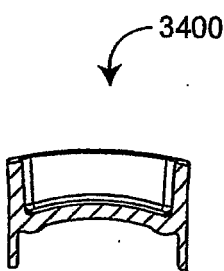


FIG. 34E



SECTION B-B

FIG. 34H

EP 2 305 104 B1

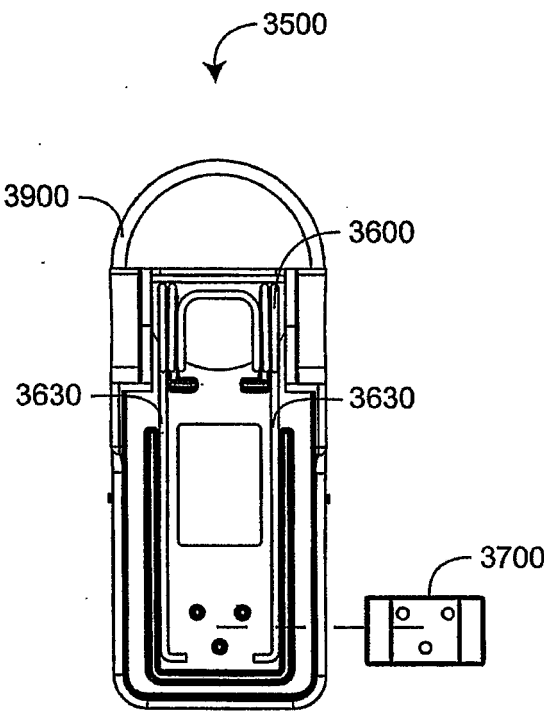


FIG. 35A

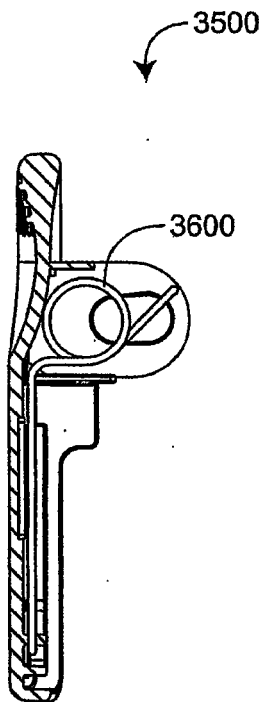


FIG. 35B

EP 2 305 104 B1

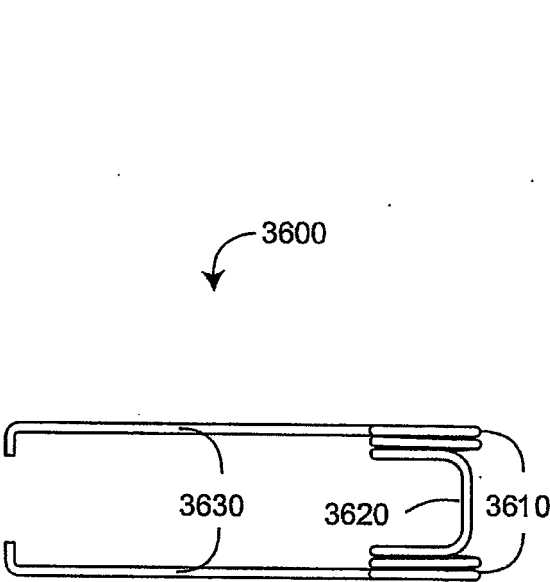


FIG. 36A

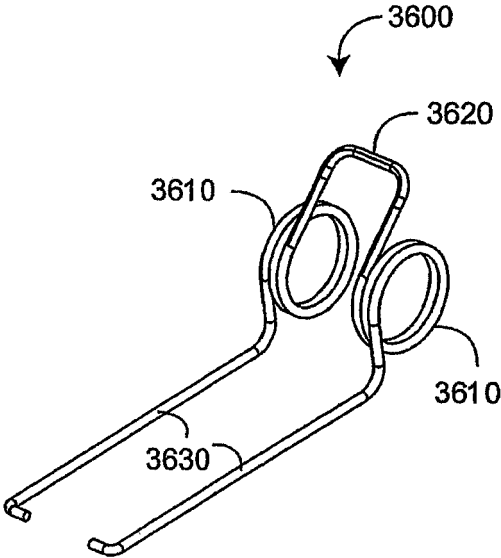


FIG. 36B

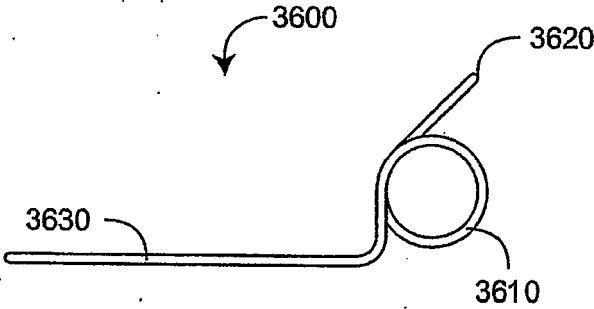


FIG. 36C

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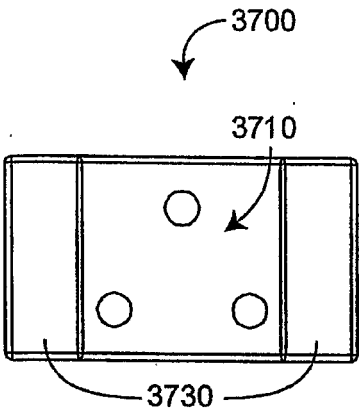


FIG. 37A

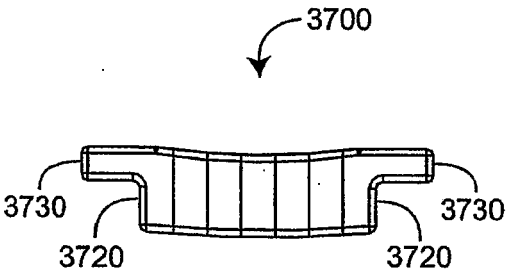


FIG. 37B

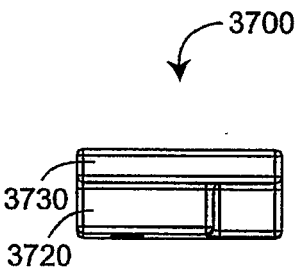


FIG. 37D

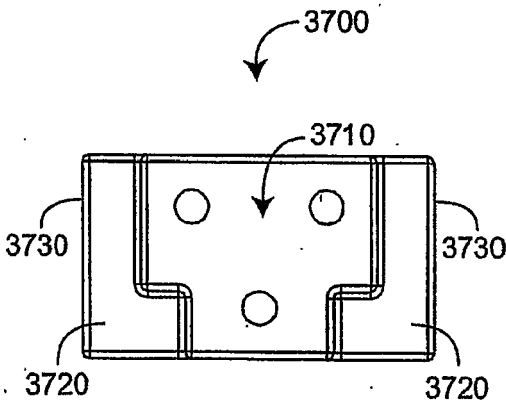


FIG. 37C

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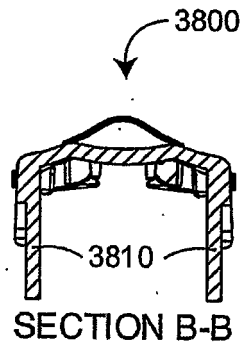


FIG. 38A

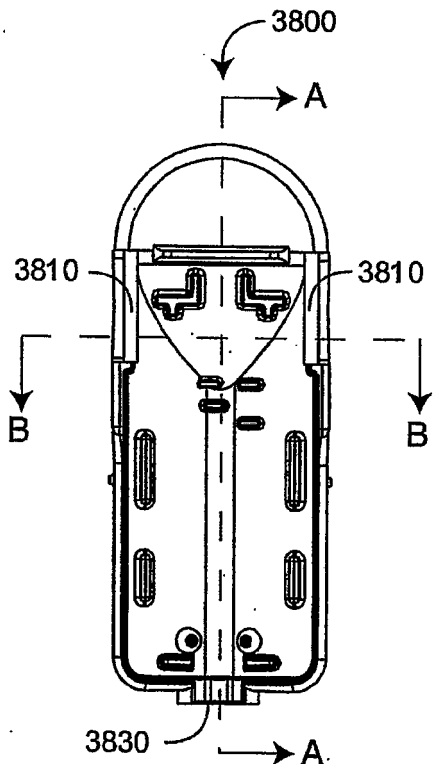


FIG. 38B

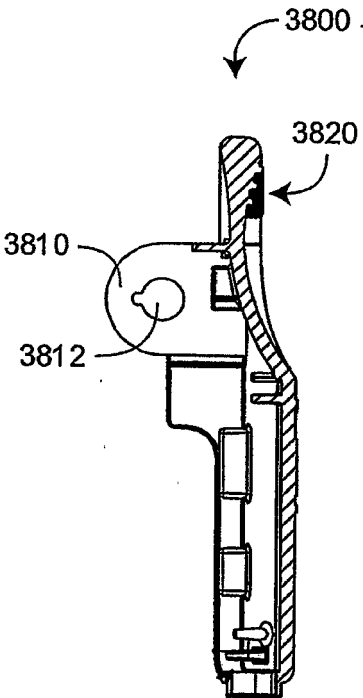


FIG. 38D

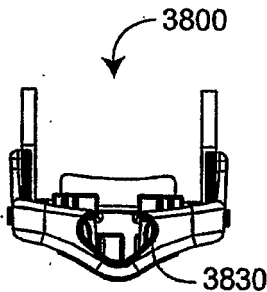


FIG. 38C

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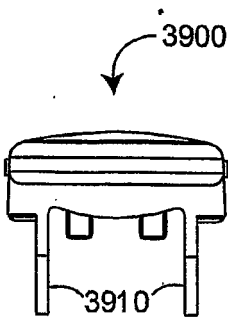


FIG. 39A

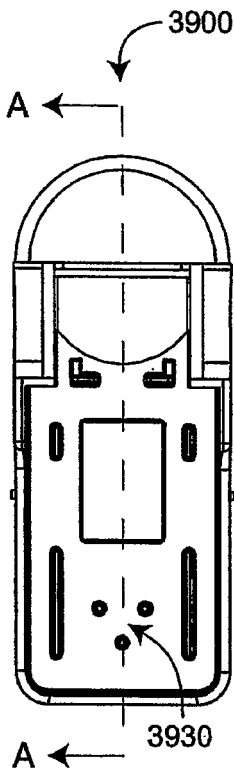
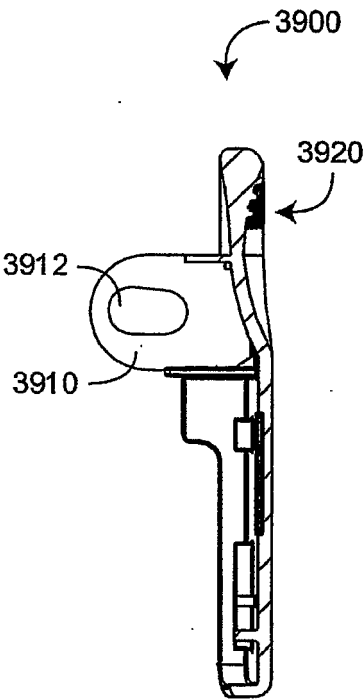


FIG. 39B



SECTION A-A
FIG. 39D

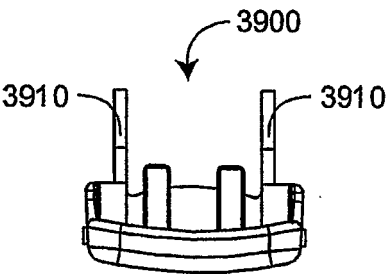


FIG. 39C

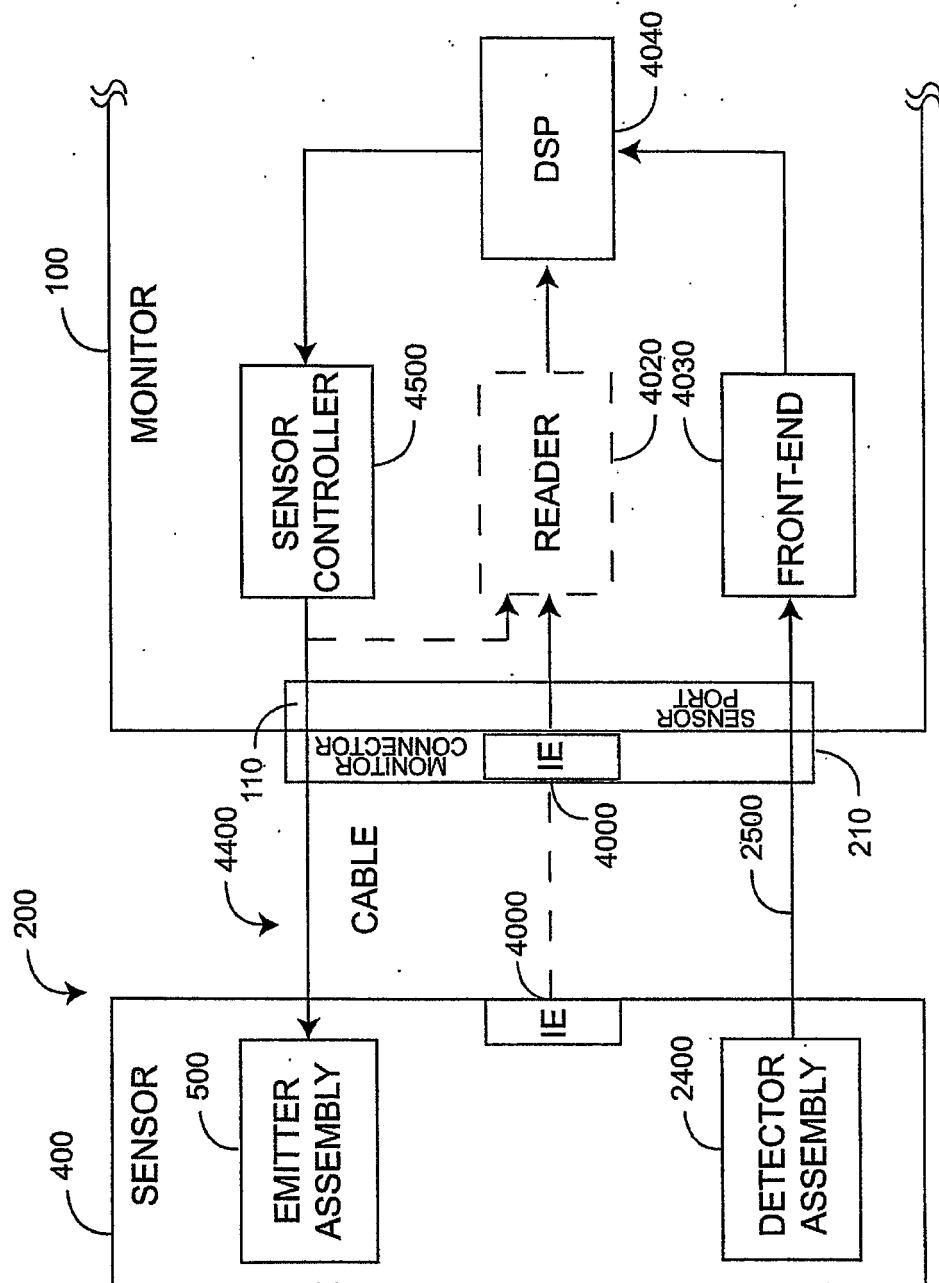


FIG. 40

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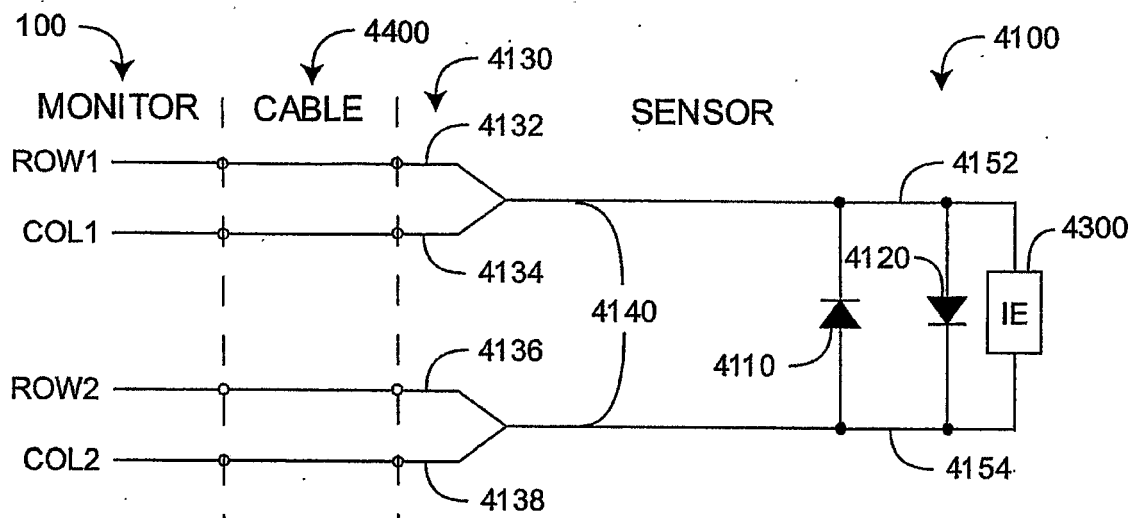


FIG. 41A

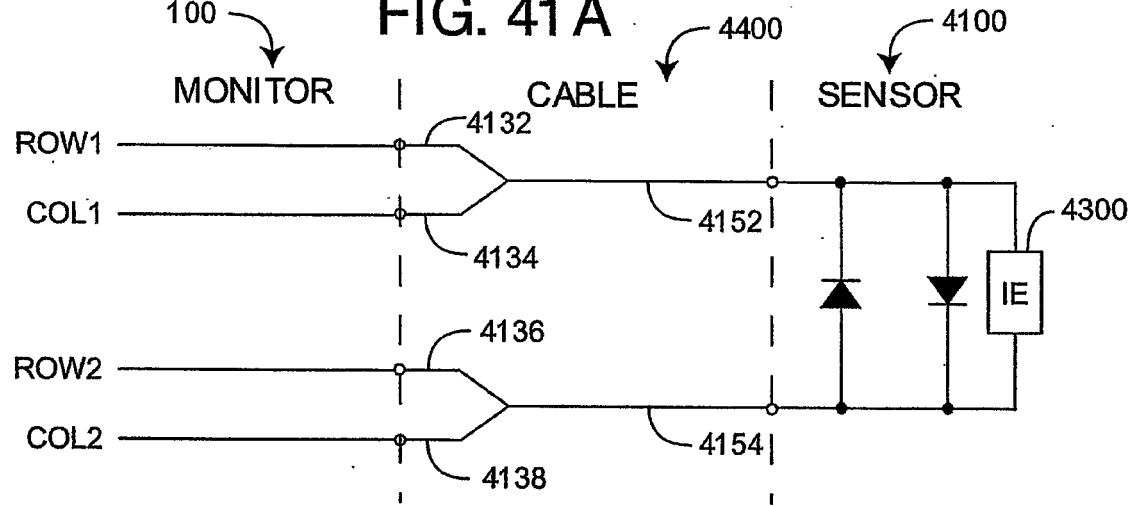


FIG. 41B

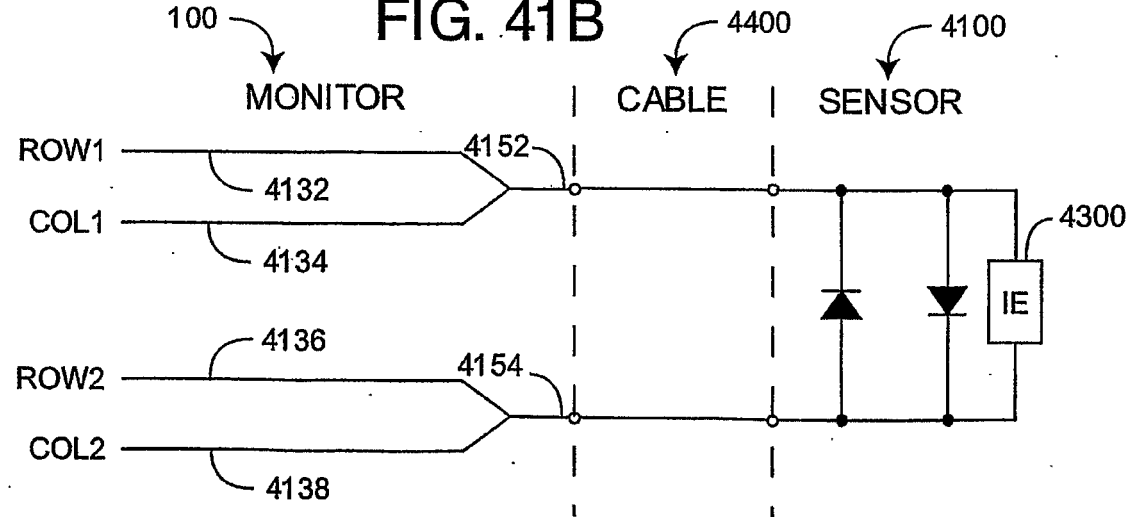
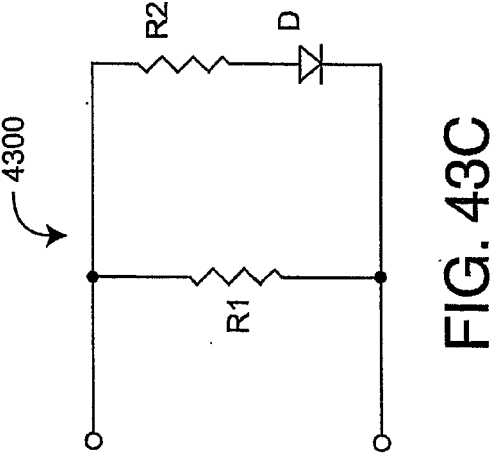
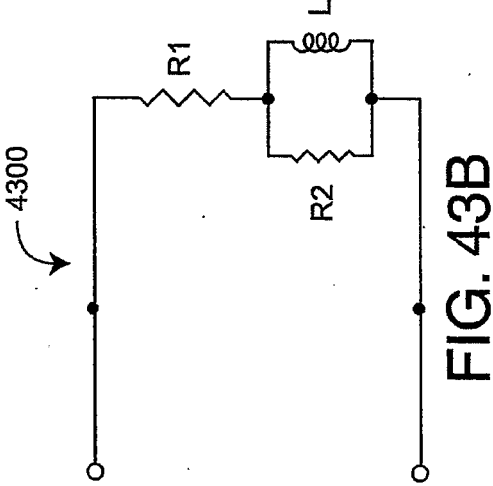
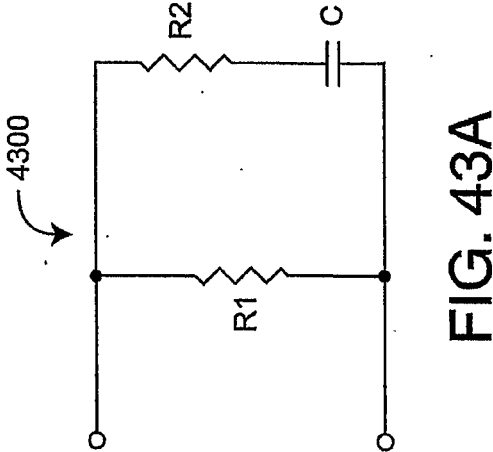
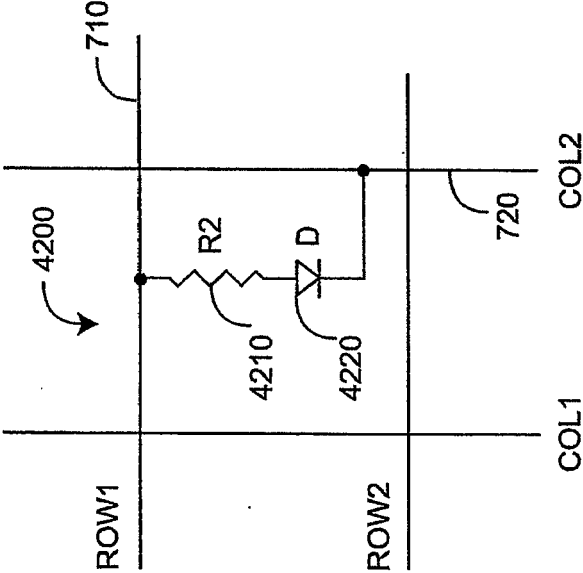


FIG. 41C

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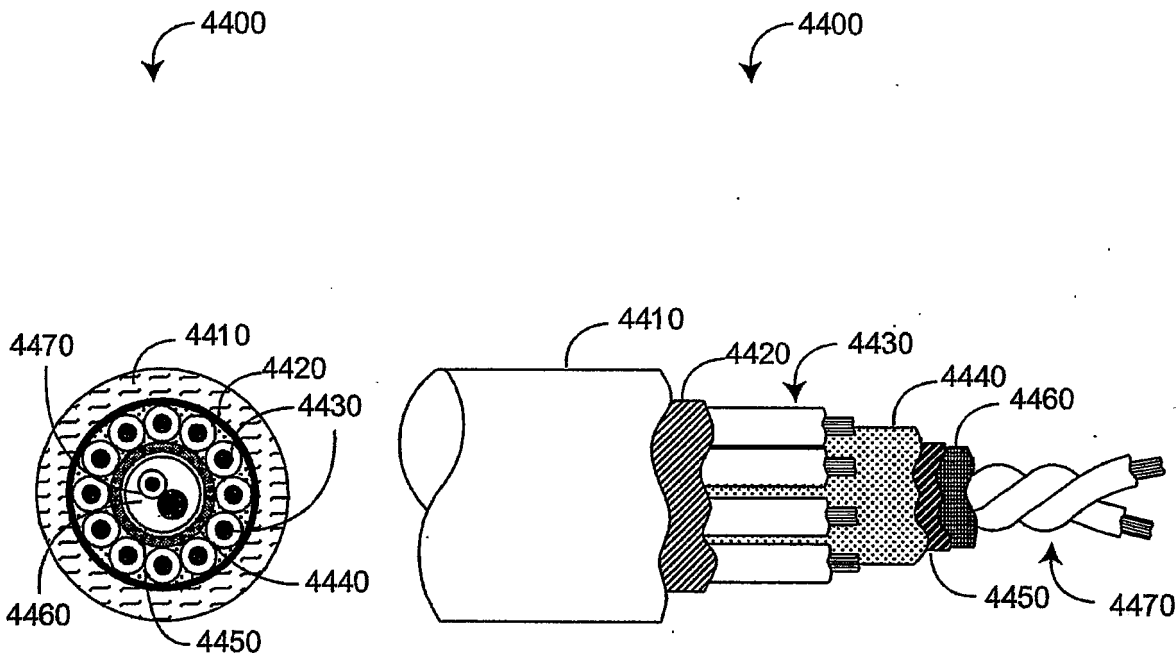


FIG. 44A

FIG. 44B

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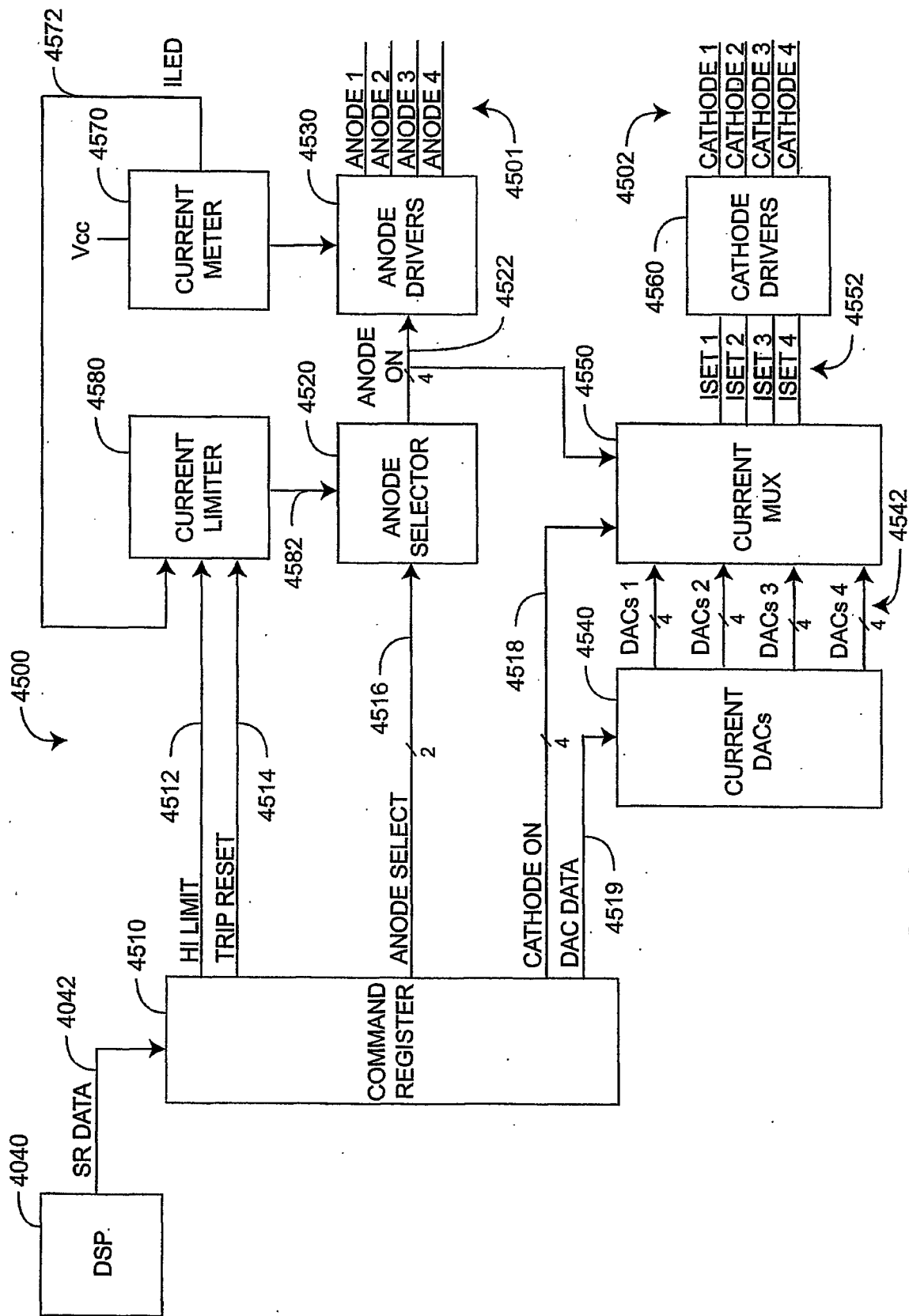


FIG. 45

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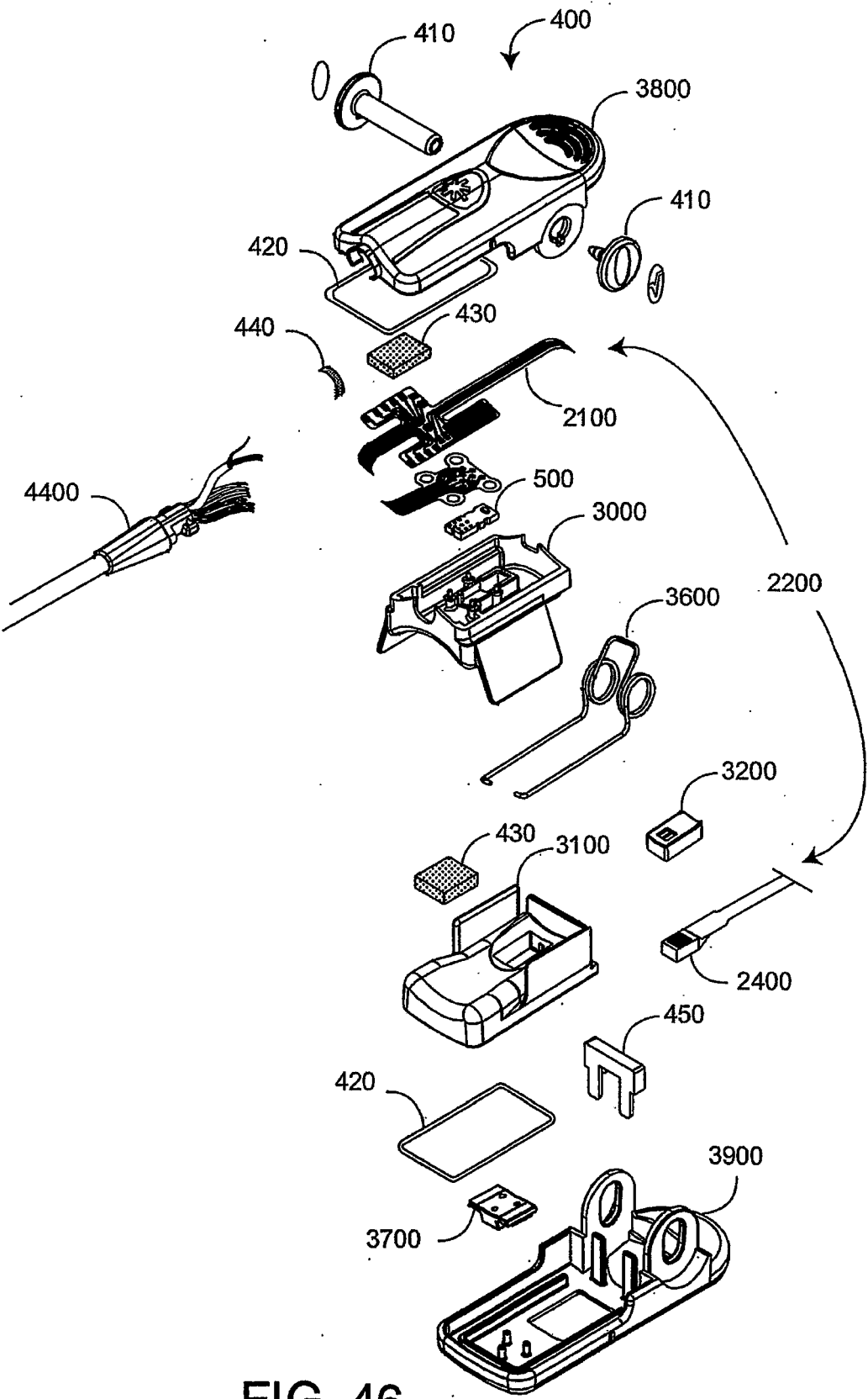


FIG. 46

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EXHIBIT 4

US007027849B2

(12) **United States Patent**
Al-Ali(10) **Patent No.:** **US 7,027,849 B2**
(45) **Date of Patent:** **Apr. 11, 2006**(54) **BLOOD PARAMETER MEASUREMENT SYSTEM**(75) Inventor: **Ammar Al-Ali**, Tustin, CA (US)(73) Assignee: **Masimo Laboratories, Inc.**, Irvine, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 5 days.

(21) Appl. No.: **10/719,928**(22) Filed: **Nov. 21, 2003**(65) **Prior Publication Data**

US 2004/0107065 A1 Jun. 3, 2004

Related U.S. Application Data

(60) Provisional application No. 60/428,419, filed on Nov. 22, 2002.

(51) **Int. Cl.**
A61B 5/00 (2006.01)(52) **U.S. Cl.** **600/323; 702/104**(58) **Field of Classification Search** **702/104, 702/127, 134, 135; 356/39-42; 600/332-342**
See application file for complete search history.(56) **References Cited****U.S. PATENT DOCUMENTS**

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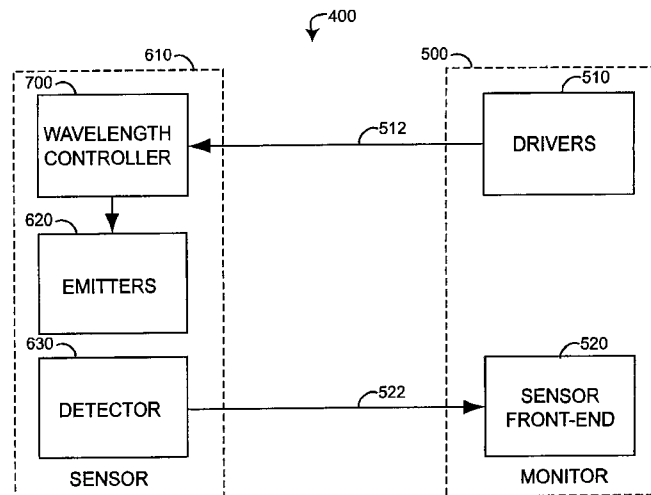
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Primary Examiner—Michael Nghiem*Assistant Examiner*—Demetrius Pretlow(74) *Attorney, Agent, or Firm*—Knobbe, Martens, Olson & Bear, LLP(57) **ABSTRACT**

A blood parameter measurement system has a monitor configured to provide an oxygen saturation measurement based upon the absorption of two wavelengths of optical radiation by a tissue site. A software upgrade is installable in the monitor so as to enable the monitor to operate in conjunction with a multiple wavelength sensor. A wavelength controller is adapted to the upgrade so as to drive the sensor.

19 Claims, 16 Drawing Sheets

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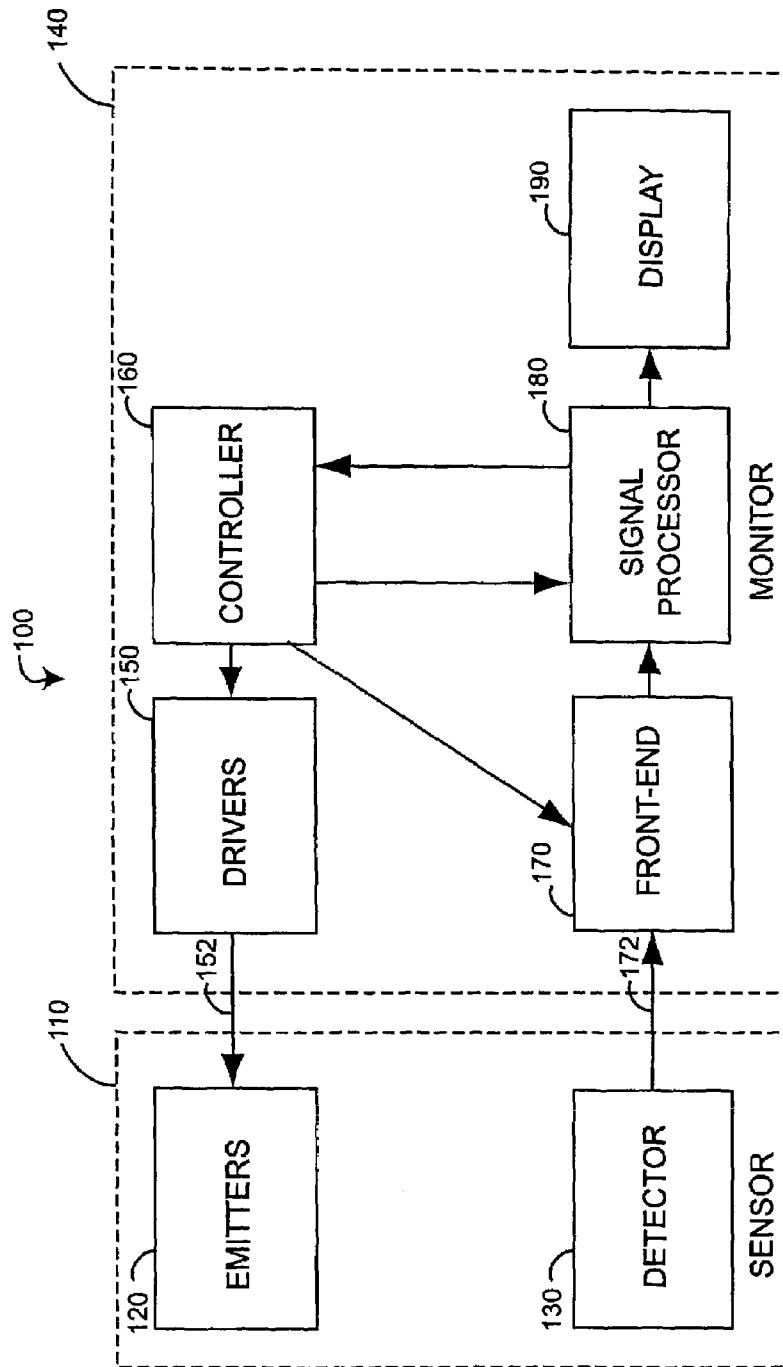


FIG. 1 (Prior Art)

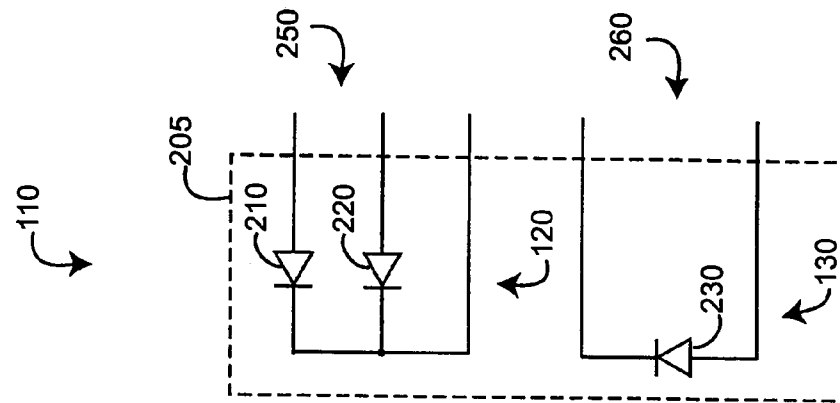


FIG. 2C

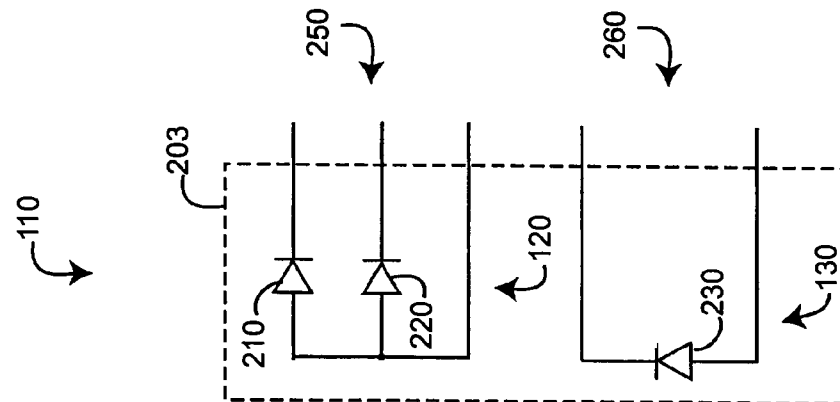


FIG. 2B

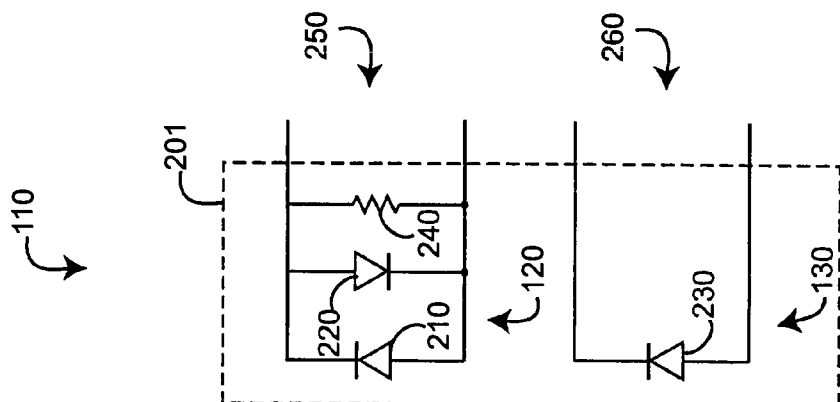


FIG. 2A

(Prior Art)

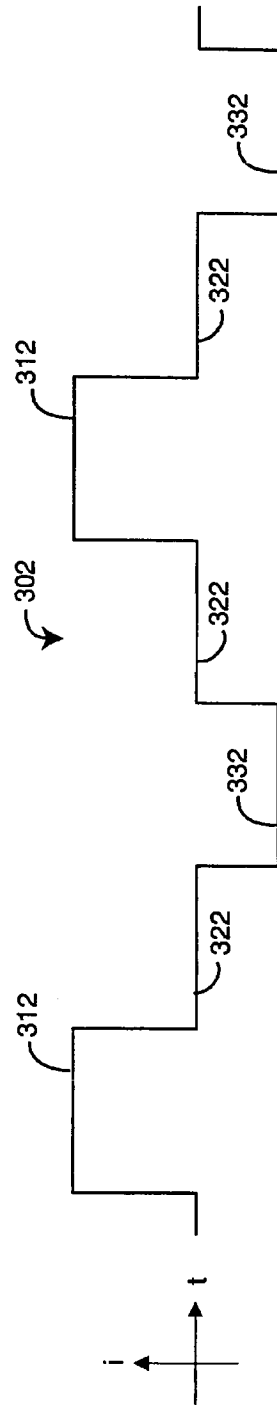
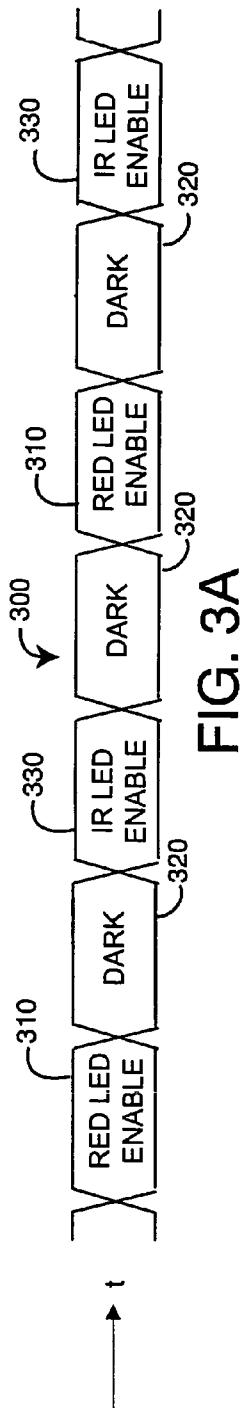


FIG. 3B

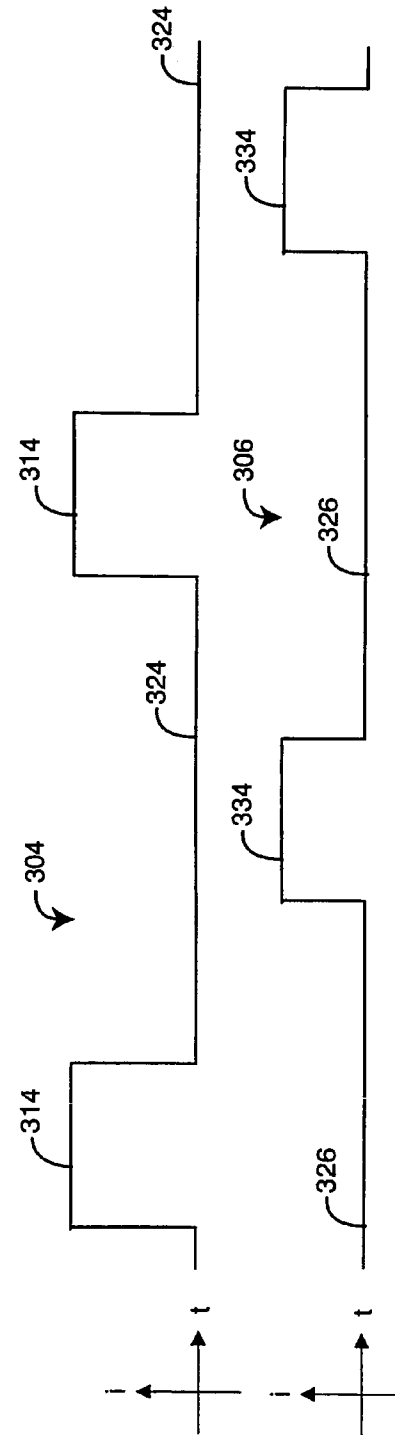


FIG. 3C

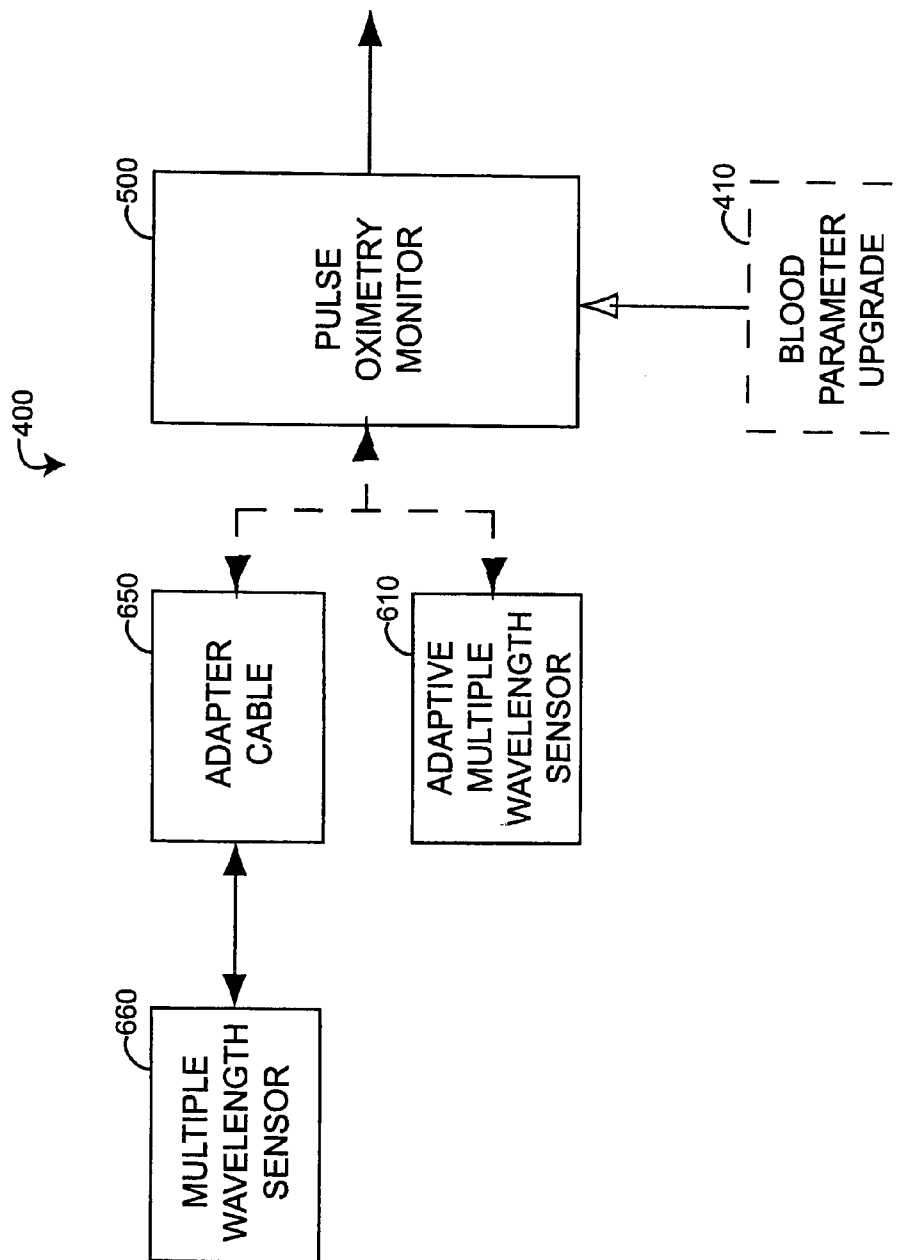


FIG. 4

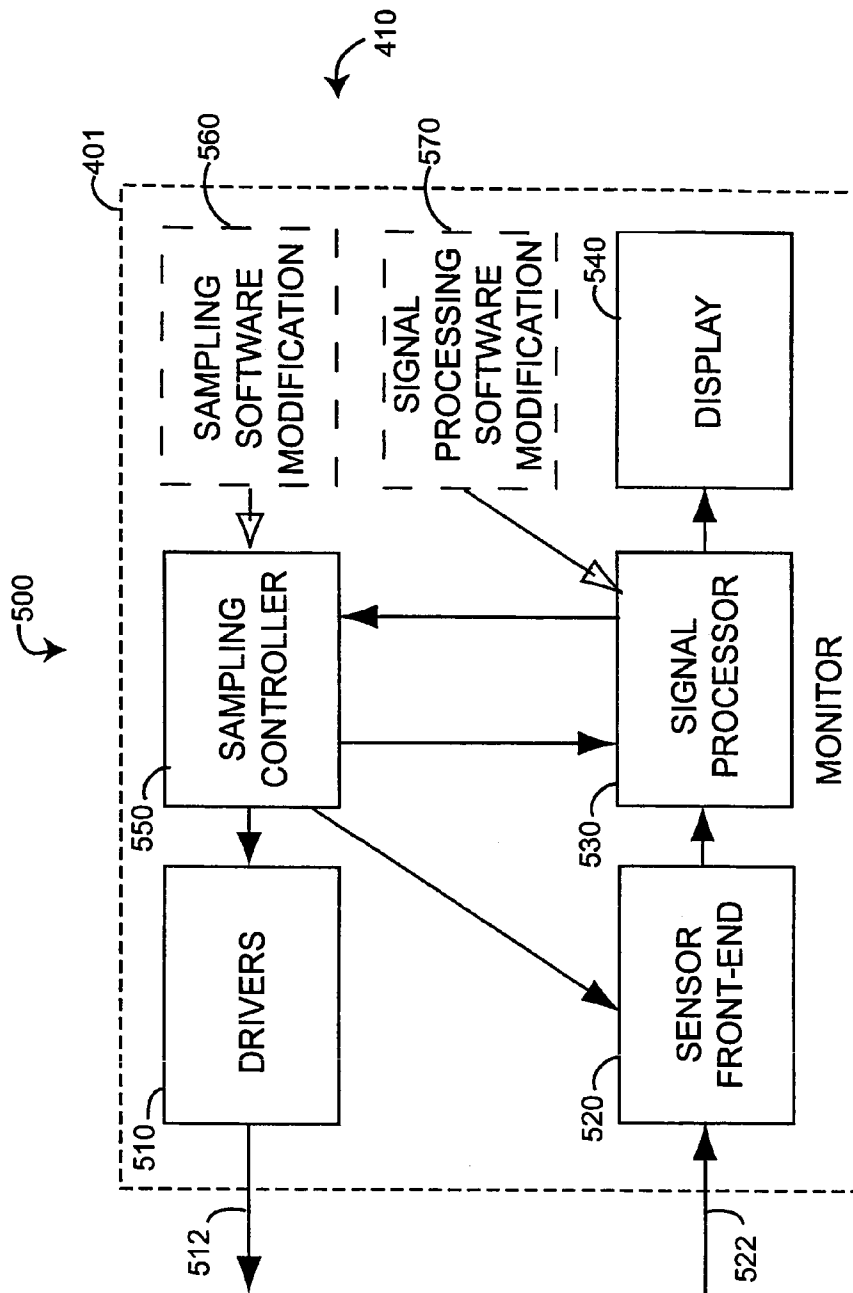


FIG. 5

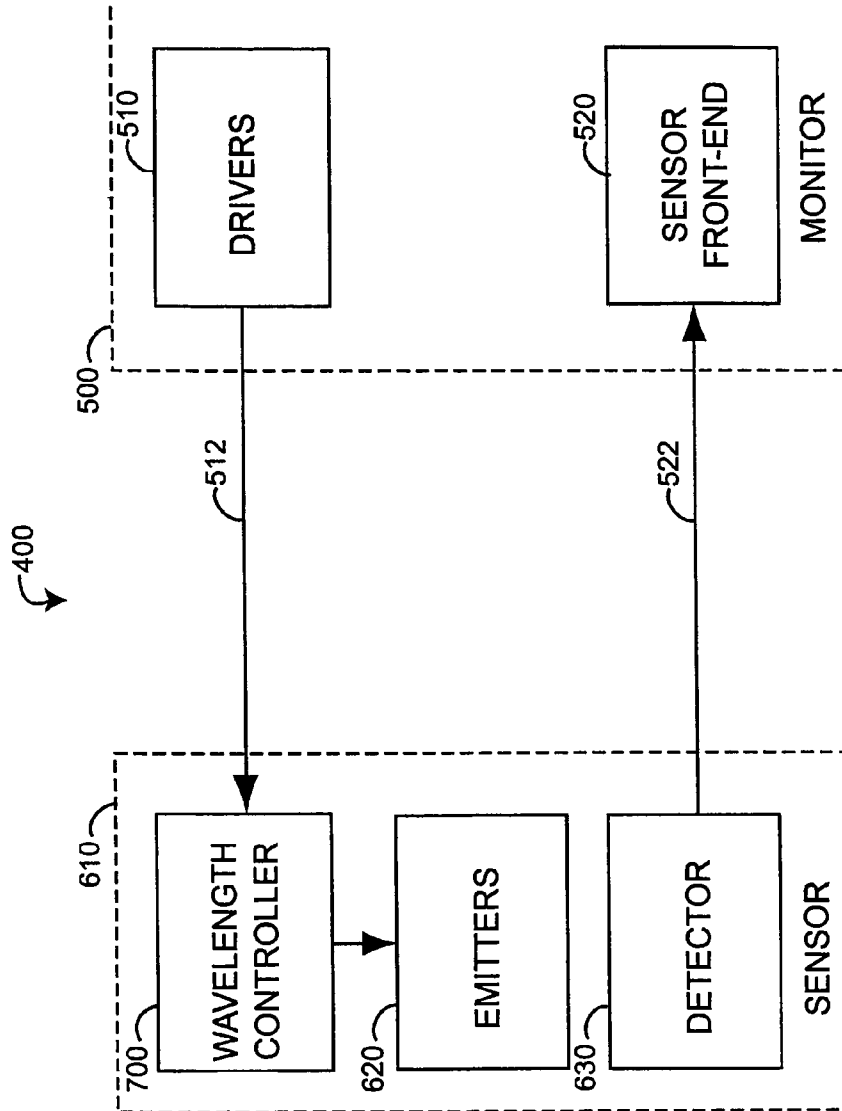


FIG. 6A

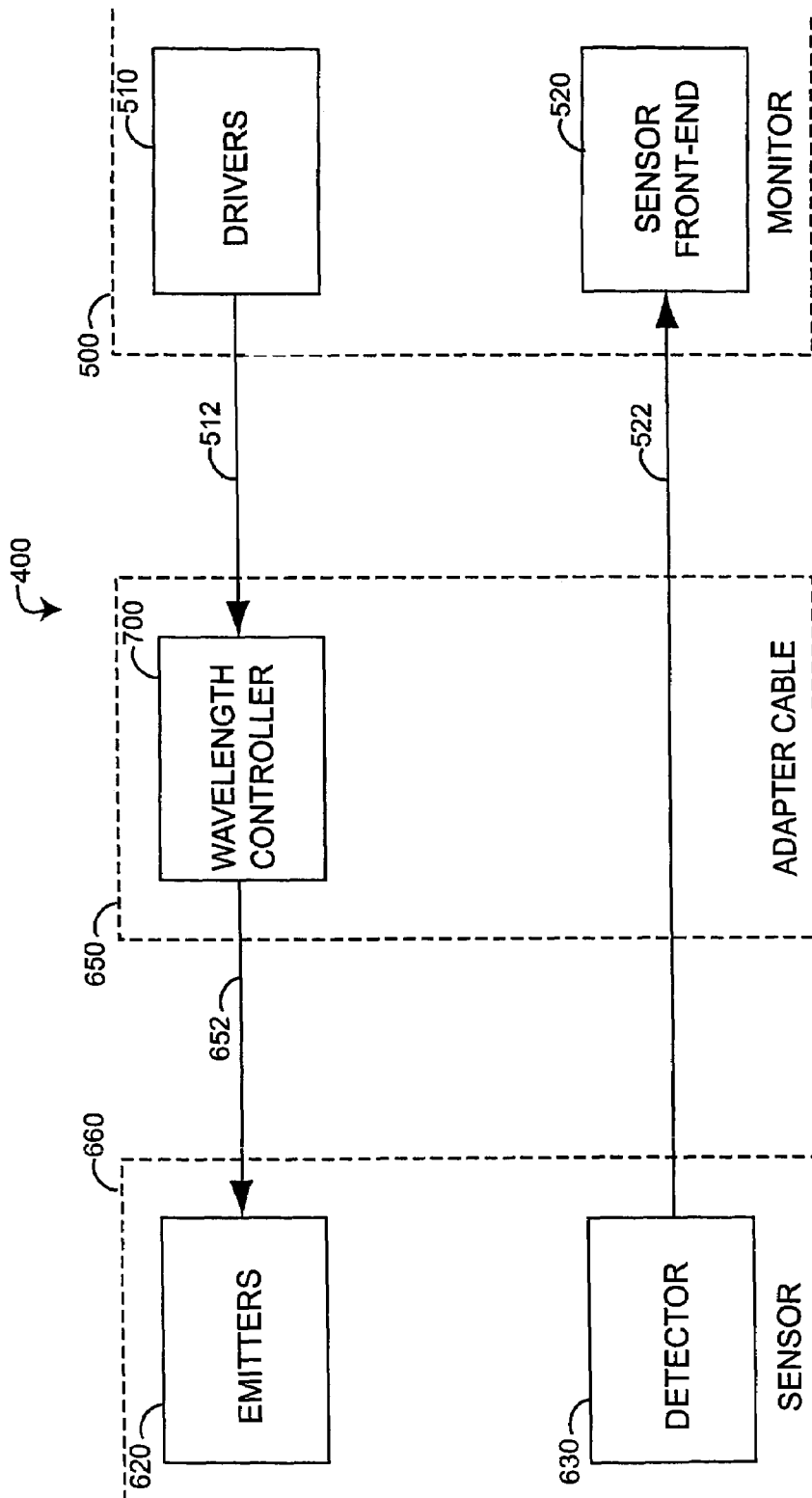


FIG. 6B

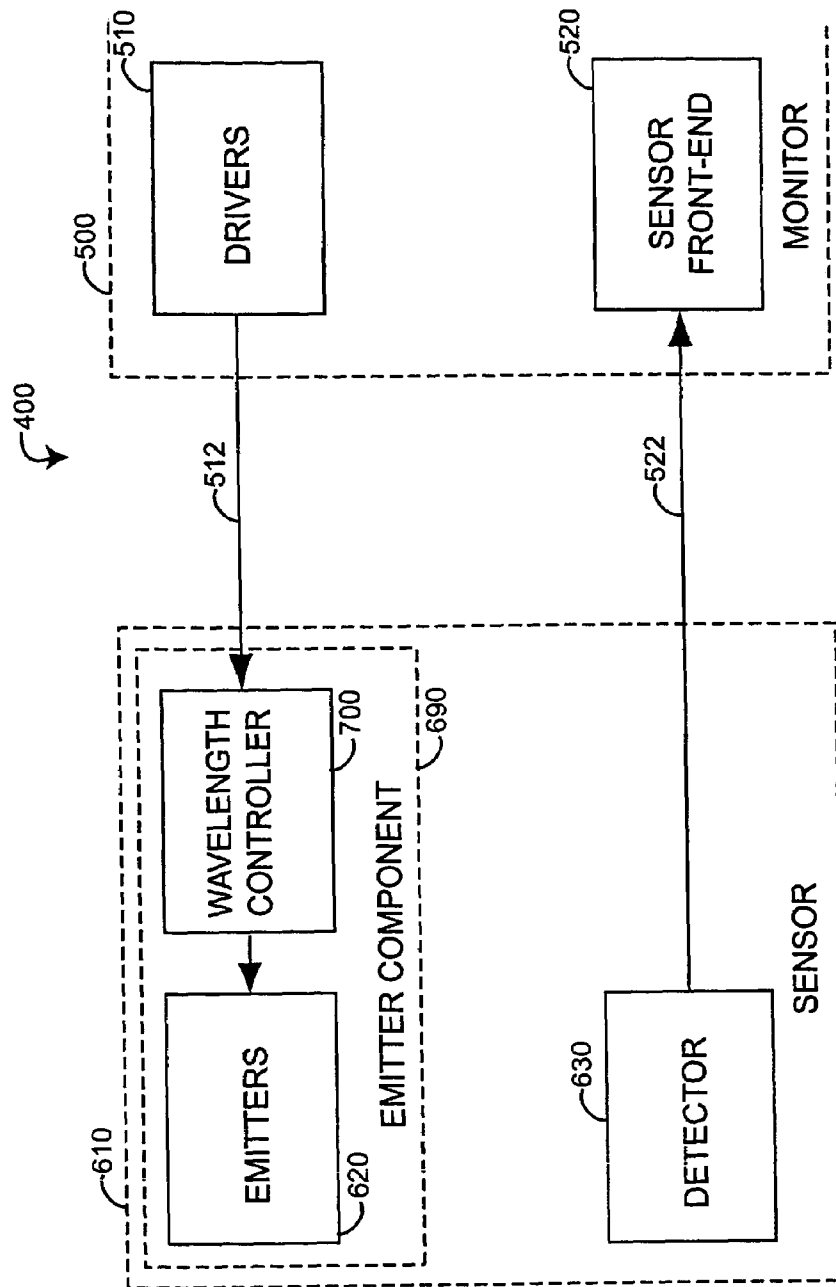


FIG. 6C

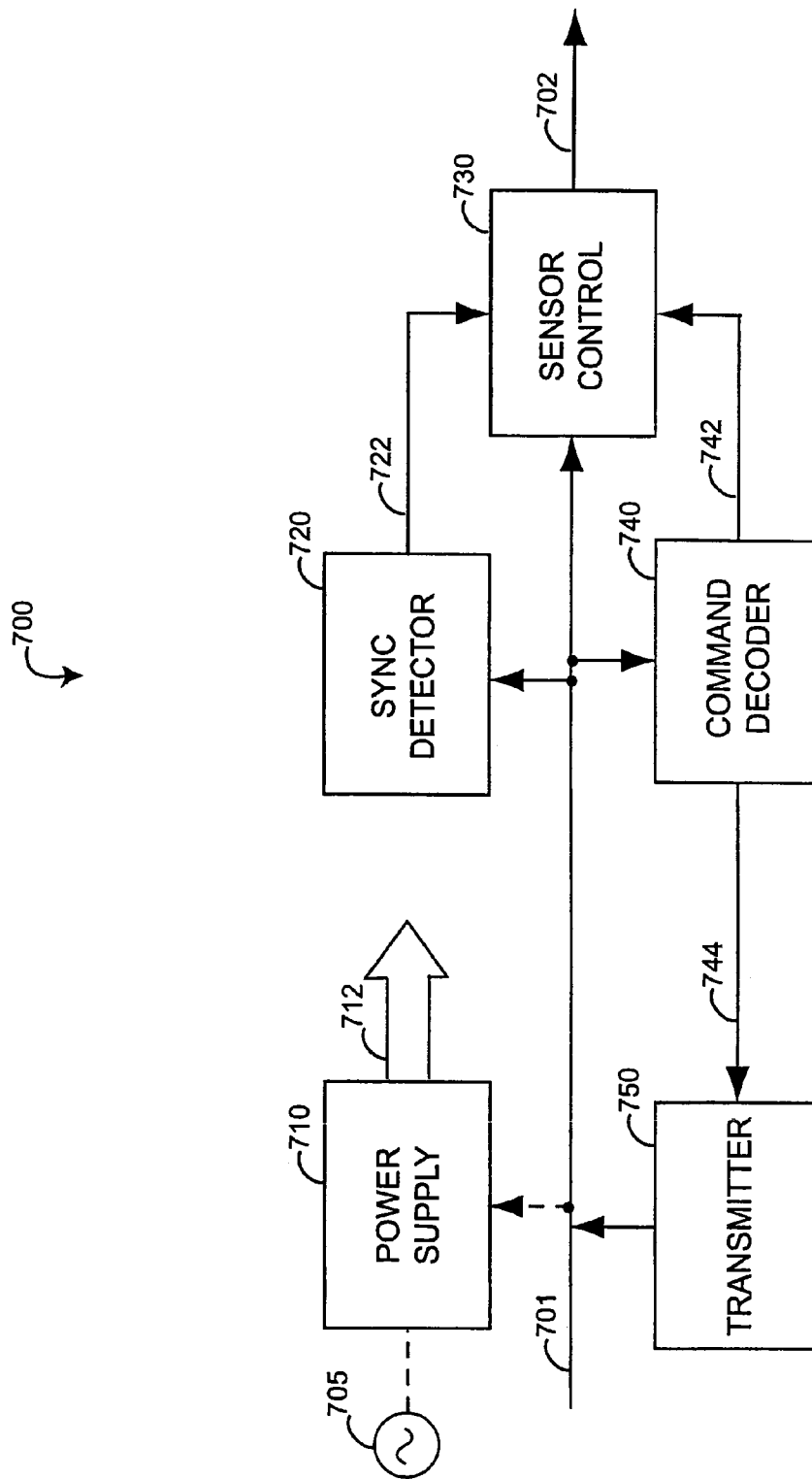


FIG. 7

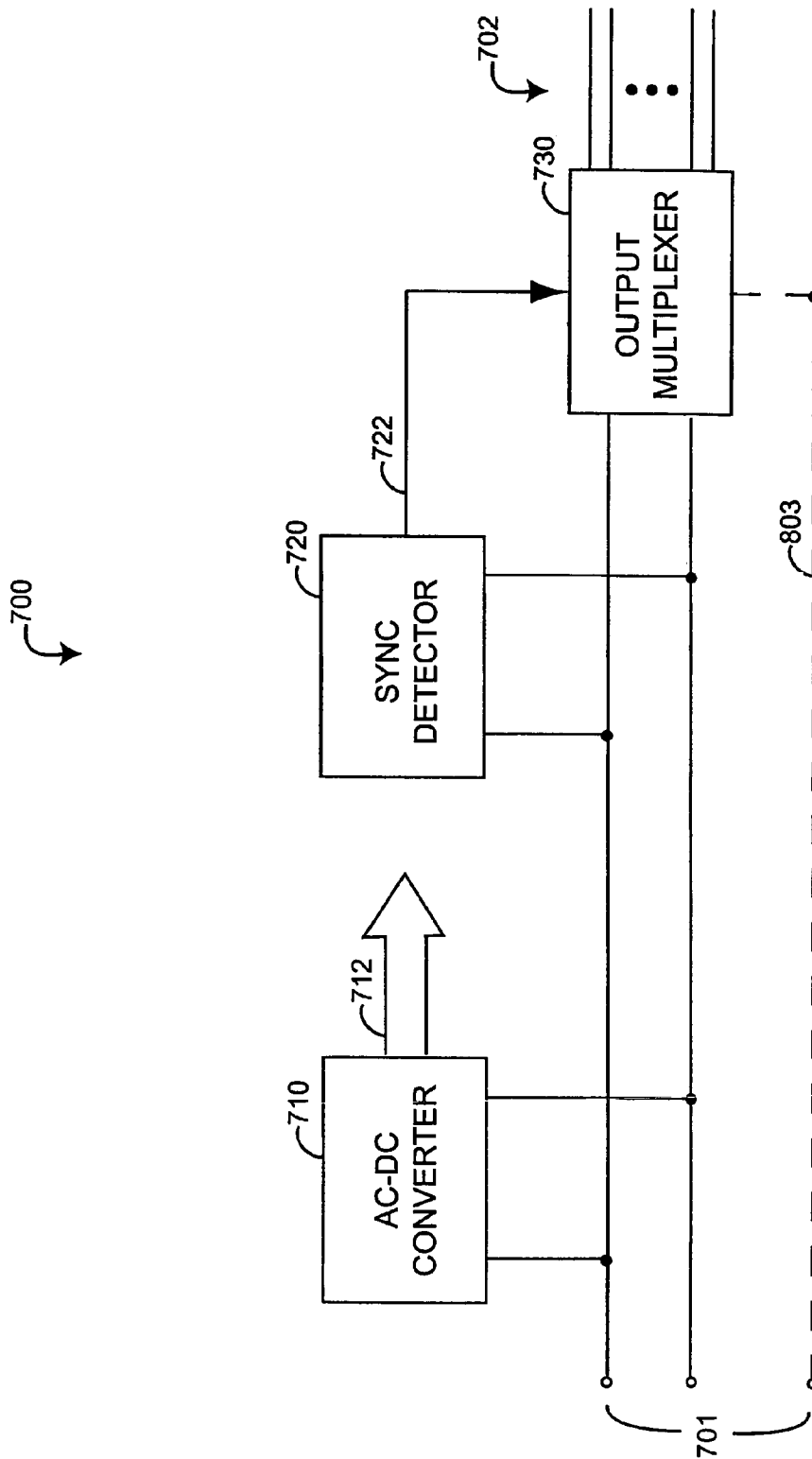


FIG. 8A

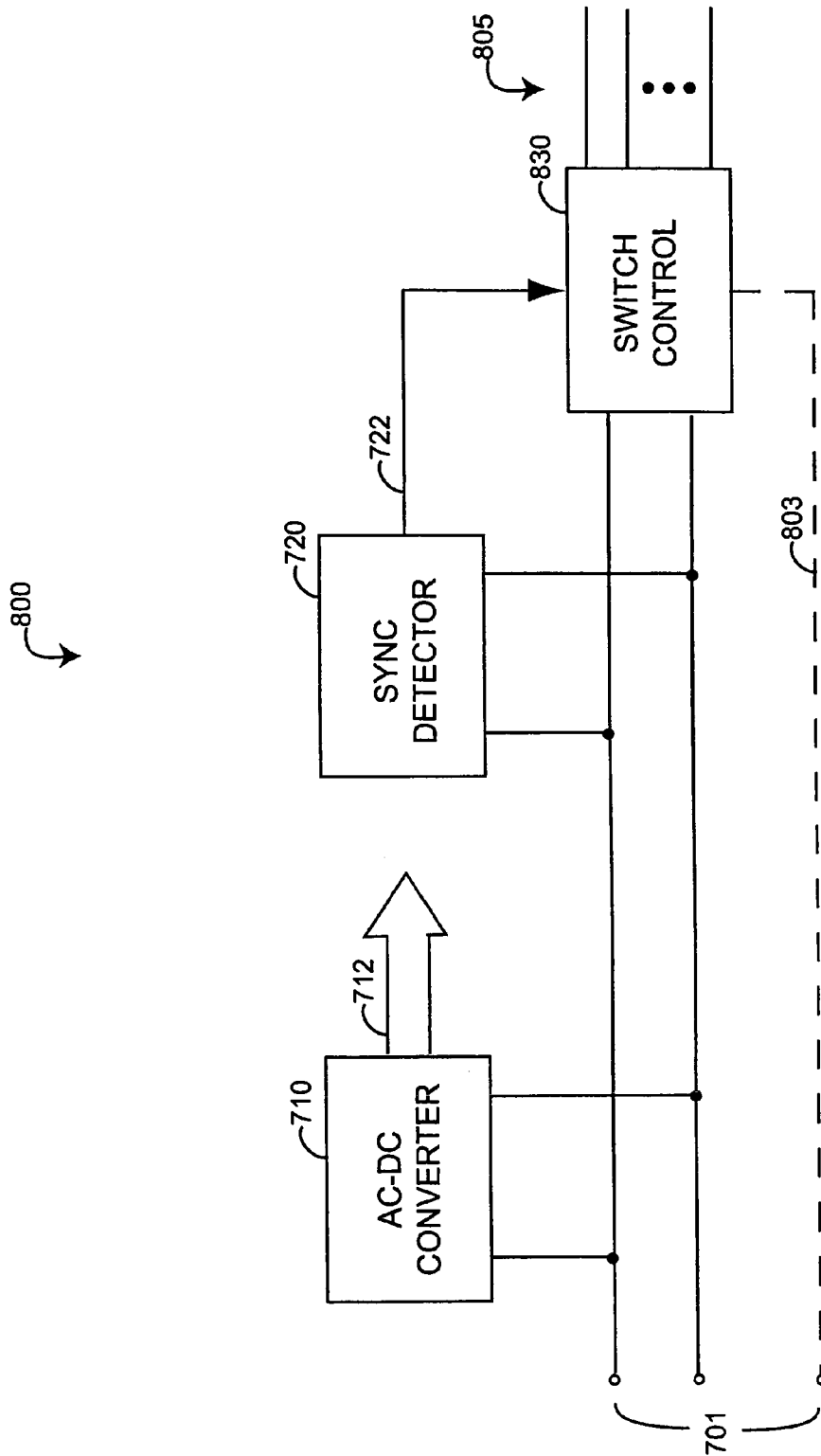
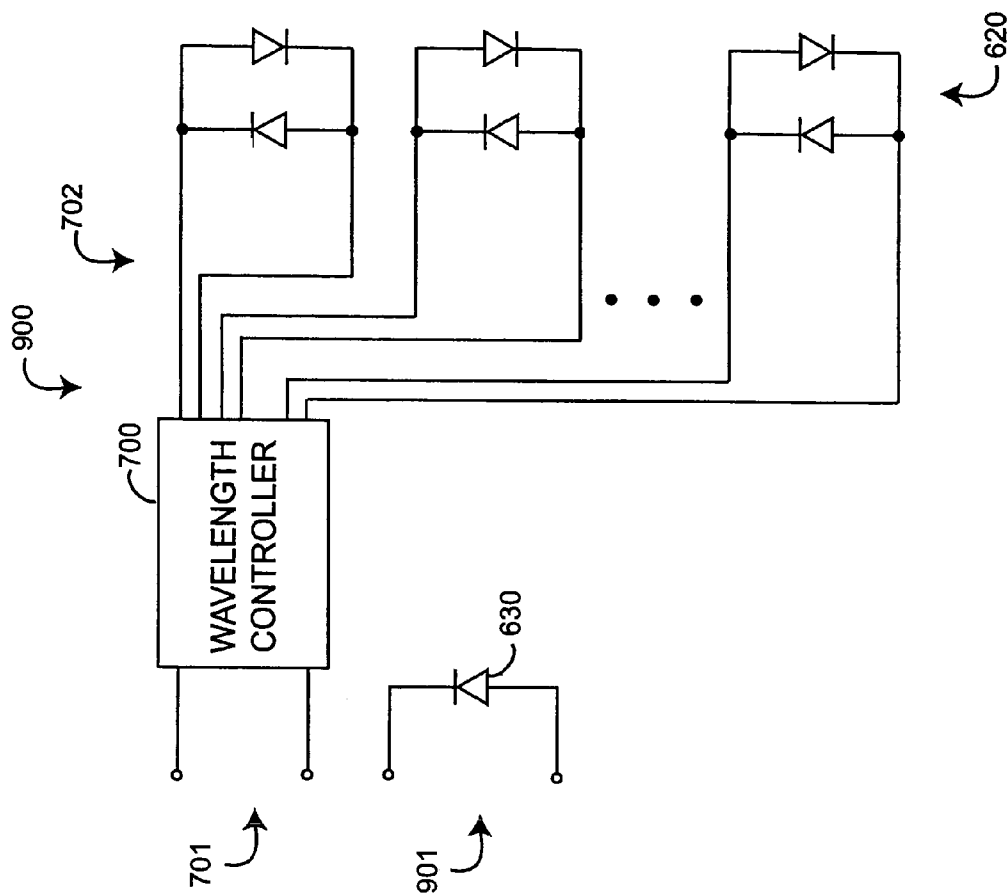


FIG. 8B



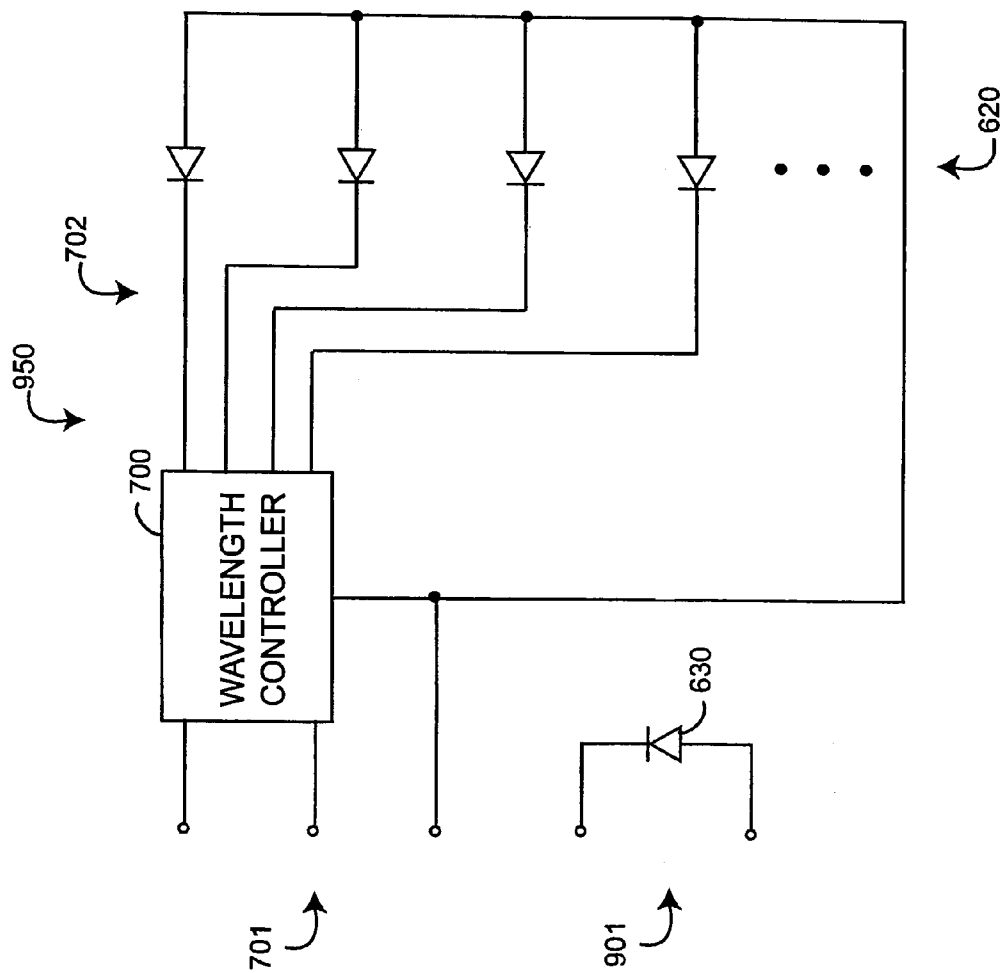


FIG. 9B

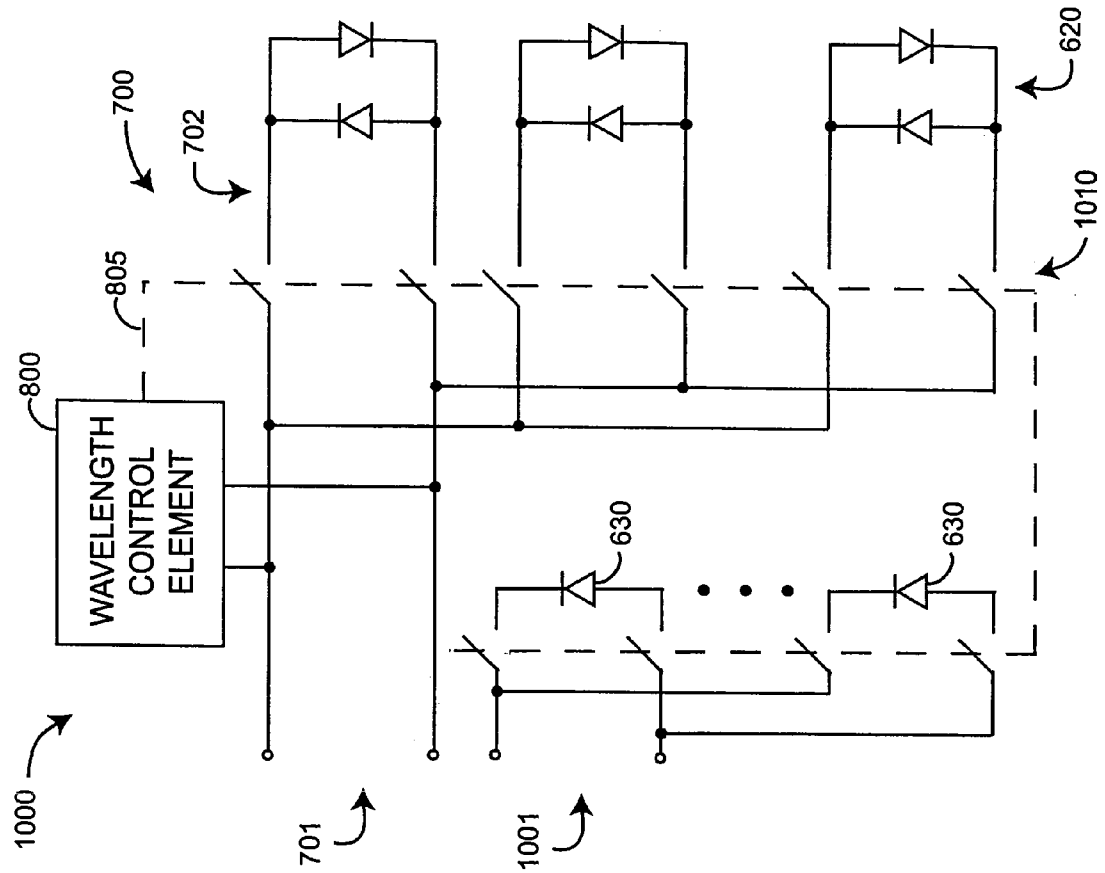


FIG. 10A

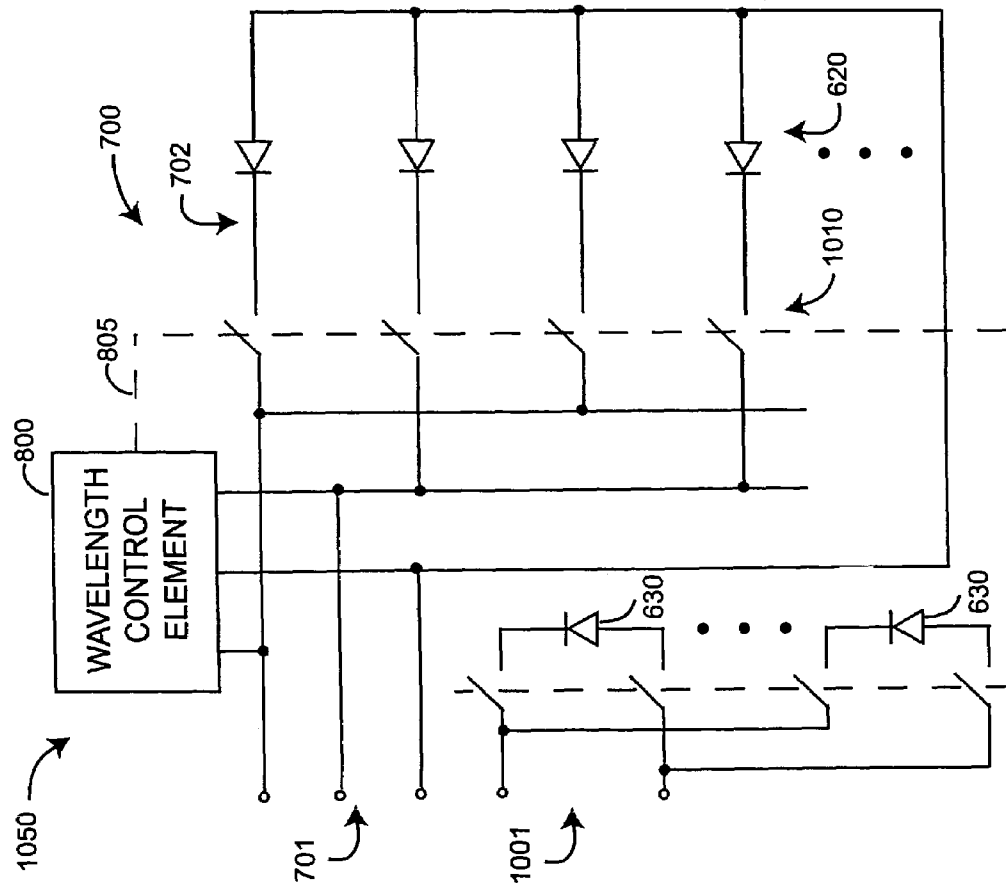


FIG. 10B

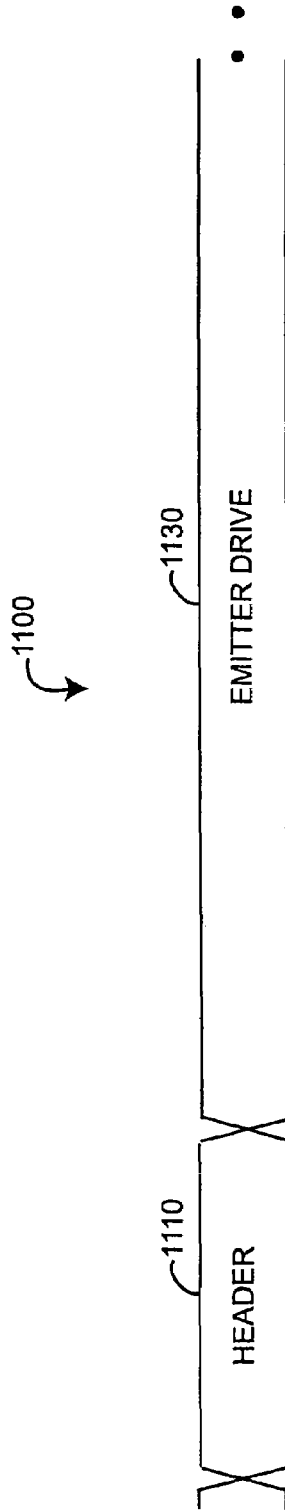


FIG. 11A

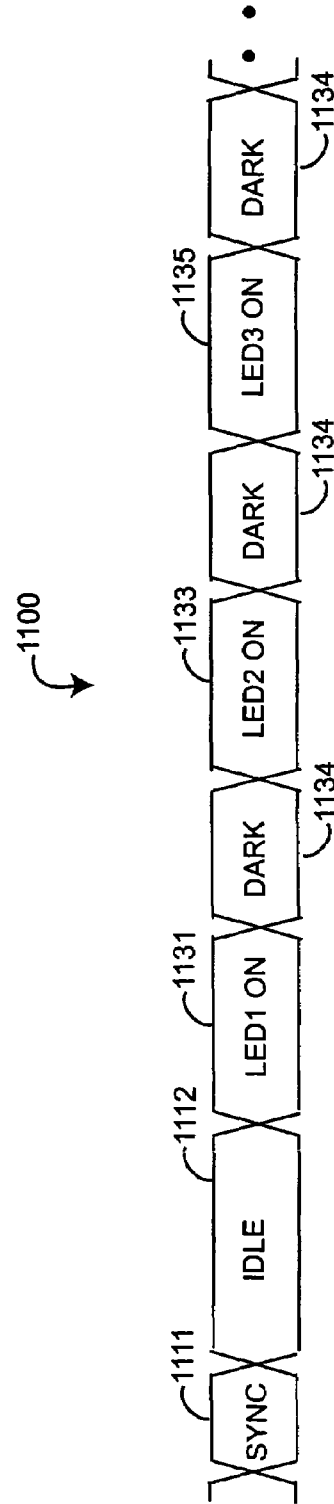


FIG. 11B

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1

**BLOOD PARAMETER MEASUREMENT
SYSTEM****CROSS-REFERENCE TO RELATED
APPLICATION**

The present application claims priority benefit under 35 U.S.C. §119(e) from U.S. Provisional Application No. 60/428,419, filed Nov. 22, 2002 entitled "Blood Parameter Measurement System," which is incorporated herein by reference.

BACKGROUND OF THE INVENTION

Pulse oximetry is a noninvasive, easy to use, inexpensive procedure for measuring the oxygen saturation level of arterial blood. Pulse oximeters perform a spectral analysis of the pulsatile component of arterial blood in order to determine the relative concentration of oxygenated hemoglobin, the major oxygen carrying constituent of blood. By providing early detection of decreases in the arterial oxygen supply, pulse oximetry reduces the risk of accidental death and injury. As a result, pulse oximeters have gained rapid acceptance in a wide variety of medical applications, including surgical wards, intensive care units, general wards and home care.

FIG. 1 illustrates a pulse oximetry system 100 having a sensor 110 and a monitor 140. The sensor 110 has emitters 120 and a detector 130 and is attached to a patient at a selected tissue site, such as a fingertip or ear lobe. The emitters 120 project light through the blood vessels and capillaries of the tissue site. The detector 130 is positioned so as to detect the emitted light as it emerges from the tissue site. A pulse oximetry sensor is described in U.S. Pat. No. 6,088,607 entitled "Low Noise Optical Probe," which is assigned to Masimo Corporation, Irvine, Calif. and incorporated by reference herein.

Also shown in FIG. 1, the monitor 140 has drivers 150, a controller 160, a front-end 170, a signal processor 180, a display 190. The drivers 150 alternately activate the emitters 120 as determined by the controller 160. The front-end 170 conditions and digitizes the resulting current generated by the detector 130, which is proportional to the intensity of the detected light. The signal processor 180 inputs the conditioned detector signal and determines oxygen saturation, as described below, along with pulse rate. The display 190 provides a numerical readout of a patient's oxygen saturation and pulse rate. A pulse oximetry monitor is described in U.S. Pat. No. 5,482,036 entitled "Signal Processing Apparatus and Method," which is assigned to Masimo Corporation, Irvine, Calif. and incorporated by reference herein.

FIGS. 2A-C illustrate various circuits 201-205 for a pulse oximetry sensor 110. A typical sensor 110 has emitters 120 including both red and infrared LEDs 210, 220 and a detector 130 consisting of a photodiode 230. LED pinouts 250 connect the LEDs 210, 220 to the drivers 150 (FIG. 1) via a patient cable (not shown). Detector pinouts 260 connect the photodiode 230 to the front-end 170 (FIG. 1) also via the patient cable. FIG. 2A illustrates a back-to-back sensor circuit 201, where the LEDs 210, 220 are connected in parallel such that the anode of one LED 210 is connected to the cathode of the other LED 220 and vice-a-versa. The sensor circuit 201 may have an information element 240, such as a resistor. The information element 240 has multiple uses depending on the manufacturer, such as an indicator sensor type. An information element is described in U.S. Pat. No. 5,758,644 entitled "Manual and Automatic Probe Cali-

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bration," which is assigned to Masimo Corporation, Irvine, Calif. and incorporated by reference herein. FIGS. 2B-C illustrate alternative sensor circuits. FIG. 2B illustrates a common anode sensor circuit 203 having LEDs 210, 220 with connected anodes provided as a common one of the pinouts 250. FIG. 2C illustrates a common cathode sensor circuit 205 having LEDs 210, 220 with connected cathodes provided as a common one of the pinouts 250.

FIGS. 3A-C illustrate drive signal timing corresponding to the sensor circuits described with respect to FIGS. 2A-C, above. FIG. 3A is a timing diagram 300 of the drive signal 152 (FIG. 1) illustrating the relative occurrence and duration of control waveforms transmitted from the drivers 150 (FIG. 1) to the emitters 120 (FIG. 1). A typical drive signal 152 (FIG. 1) has a red LED enable period 310, an IR LED enable period 330 and a dark period 320 between the enable periods 310, 330. During an enable time period 310, 330, drive current is supplied from the drivers 150 (FIG. 1) to one of the LED emitters 210, 220 (FIGS. 2A-C), causing the selected LED to turn on and emit optical energy at a particular wavelength (red or IR), which is transmitted into a tissue site. During a dark period 320, no drive current is supplied to the LEDs 210, 220 (FIGS. 2A-C), turning both off. Red LED enable periods 310 are alternated with IR LED enable periods 330 so that concurrent tissue site responses at both red and IR wavelengths can be measured. The timing diagram 300 illustrates a typical 25% "on" duty cycle for a particular LED. The dark periods 320 allow the signal processor 180 (FIG. 1) to demodulate or separate the red wavelength response from the IR wavelength response. Detector signal demodulation is described in U.S. Pat. No. 5,919,134 entitled "Method and Apparatus for Demodulating Signals in a Pulse Oximetry System," which is assigned to Masimo Corporation, Irvine, Calif. and incorporated by reference herein.

FIG. 3B is a graph 302 of drive current versus time for a back-to-back sensor circuit 201 (FIG. 2A), corresponding to the timing diagram 300 (FIG. 3A), described above. During the red LED enable periods 310 (FIG. 3A), the drive signal 152 (FIG. 1) has a first polarity drive current 312 of a first amplitude, so that the red LED emits at a predetermined intensity. During the IR LED enable time periods 330 (FIG. 3A), the drive signal 152 (FIG. 1) has an second, opposite polarity drive current 332 of a second amplitude, so that the IR LED emits at a predetermined intensity. During the dark periods 320 (FIG. 3A) the drive signal 152 (FIG. 1) has no drive current 322. In this manner, the timing and intensity of the red and IR LED emissions may be independently controlled with a single drive signal 152 (FIG. 1) having bipolar drive current communicated over a single pair of conductors connected to the LED pinouts 250 (FIG. 2A).

FIG. 3C are two graphs 304, 306 of drive current versus time for a common cathode sensor circuit 205 (FIG. 2C) or, similarly, for a common anode sensor circuit 203 (FIG. 2B), corresponding to the timing diagram 300 (FIG. 3A), described above. During the red LED enable periods 310 (FIG. 3A), one drive signal 152 (FIG. 1) has a drive current 314 of a first amplitude, so that the red LED emits at a predetermined intensity. During the IR LED enable time periods 330 (FIG. 3A), another drive signal 152 (FIG. 1) has a drive current 334 of a second amplitude, so that the IR LED emits at a predetermined intensity. During the dark periods 320 (FIG. 3A) the drive signals 152 (FIG. 1) have no drive current 324, 326. In this manner, the timing and intensity of the red and IR LED emissions may be independently controlled with two drive signals 152 (FIG. 1) each having unipolar drive current communicated over three

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conductors, including a common conductor, connected to the LED pinouts **250** (FIG. 2C).

SUMMARY OF THE INVENTION

The Beer-Lambert law provides a simple model that describes a tissue site response to pulse oximetry measurements. The Beer-Lambert law states that the concentration c_i of an absorbent in solution can be determined by the intensity of light transmitted through the solution, knowing the pathlength d_{λ} , the intensity of the incident light $I_{0,\lambda}$, and the extinction coefficient $\epsilon_{i,\lambda}$ at a particular wavelength λ . In generalized form, the Beer-Lambert law is expressed as:

$$I_{\lambda} = I_{0,\lambda} e^{-d_{\lambda} \mu_{a,\lambda}} \quad (1)$$

$$\mu_{a,\lambda} = \sum_{i=1}^n \epsilon_{i,\lambda} \cdot c_i \quad (2)$$

where $\mu_{a,\lambda}$ is the bulk absorption coefficient and represents the probability of absorption per unit length. The minimum number of discrete wavelengths that are required to solve EQS. 1-2 are the number of significant absorbers that are present in the solution. For pulse oximetry, wavelengths are chosen such that, normally, there are only two significant absorbers. These are oxygenated hemoglobin (HbO₂) and deoxygenated hemoglobin (Hb). Thus, pulse oximetry measurements are conventionally made at two wavelengths including a red wavelength, such as 660 nm, and an infrared wavelength, such as 940 nm.

There is a need to provide a noninvasive, easy to use, inexpensive procedure to measure multiple blood parameters, other than, or in addition to, HbO₂ and Hb. For example, hemoglobin species that are also significant under certain circumstances are carboxyhemoglobin (HbCO) and methemoglobin (MetHb). Other blood parameters that may be measured to provide important clinical information are blood glucose and total hematocrit (Hct), to name a few. An advantageous solution is to provide a software upgrade for conventional pulse oximetry so as to achieve multiple-wavelength capability, that is, the ability to measure tissue site response to optical radiation of three or more wavelengths. Such a software upgrade can be readily applied to current pulse oximetry system designs and to the widespread installed base of pulse oximeters and multiparameter patient monitors to increase measurement capabilities to include a range of important blood parameters in addition to, or instead of, oxygen saturation.

One aspect of a blood parameter measurement system is a monitor configured to provide an oxygen saturation measurement based upon the absorption of two wavelengths of optical radiation by a tissue site. A software upgrade is installable in the monitor so as to enable the monitor to operate in conjunction with a multiple wavelength sensor. A wavelength controller is adapted to the upgrade so as to drive the sensor.

Another aspect of a blood parameter measurement system is a multiplicity of emitters configured to transmit at least three distinct wavelengths of optical radiation into a tissue site. At least one detector is configured to receive the radiation after attenuation by the tissue site and to generate a corresponding detector signal output. A wavelength controller has a drive signal input and a sensor control output and is adapted to sequentially enable the emitters.

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A further aspect of a blood parameter measurement system is a method having the steps of communicating a drive signal from a monitor to a sensor and synchronizing the sensor with the monitor. Additional steps include sequentially enabling a plurality of emitters of the sensor and communicating a sensor signal from the sensor to the monitor.

An additional aspect of a blood parameter measurement system is a multiple wavelength sensor means for illuminating a tissue site with at least three wavelengths and detecting a corresponding tissue site response. The system includes a software upgrade means for enabling a pulse oximetry monitor to drive the sensor and process a corresponding sensor signal. The system also includes a wavelength controller means for interfacing between the software upgrade means and the multiple wavelength sensor means.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is block diagram of a prior art pulse oximetry system;

FIGS. 2A–C are schematic diagrams of prior art sensor circuits;

FIGS. 3A–C are a timing diagrams illustrating drive current waveforms for prior art sensor circuits;

FIG. 4 is a block diagram of a blood parameter measurement system utilizing a software upgrade to a pulse oximetry monitor;

FIG. 5 is a block diagram of a monitor incorporating a blood parameter software upgrade;

FIGS. 6A–C are block diagrams of wavelength controller configurations for interfacing a multiple wavelength sensor to an upgraded monitor;

FIG. 6A is a block diagram of a blood parameter measurement system having a wavelength controller in an adaptive sensor;

FIG. 6B is a block diagram of a blood parameter measurement system having a wavelength controller in an adapter cable;

FIG. 6C is a block diagram of a blood parameter measurement system having a wavelength controller incorporated within an emitter component of an adaptive sensor;

FIG. 7 is a top-level block diagram of a wavelength controller;

FIGS. 8A–B are detailed block diagrams of a wavelength controller embodiment and a wavelength control element embodiment of a wavelength controller portion, respectively;

FIGS. 9A–B are schematic diagrams of a multiple wavelength sensor incorporating a wavelength controller;

FIGS. 10A–B are schematic diagrams of a multiple wavelength sensor incorporating a wavelength control element and corresponding switches; and

FIGS. 11A–B are multiple-wavelength timing diagrams.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

FIG. 4 illustrates a blood parameter measurement system **400** having a pulse oximetry monitor **500** and a blood parameter upgrade **410**. The monitor **500** may be any pulse oximeter configured to calculate and output oxygen saturation measurements utilizing a red and IR wavelength sensor attached to a tissue site, such as described with respect to FIGS. 1–3, above. Advantageously, the monitor **500** is enabled to measure blood parameters in addition to or in lieu of oxygen saturation by a blood parameter upgrade **410** to

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the monitor software, without the necessity of a monitor hardware modification. In particular, the upgrade 410 enables the monitor 500 to drive a multiple wavelength sensor and to process the corresponding sensor output.

As shown in FIG. 4, the blood parameter measurement system 400 also has an adaptive multiple wavelength sensor 610 or an adapter cable 650 as alternative sensor port connections to the upgraded monitor 500. The adaptive sensor 610 is plug compatible with the monitor and functionally compatible with the blood parameter upgrade so as to provide multiple wavelength capability to the measurement system 400. The adapter cable 650 is also plug compatible with the monitor and functionally compatible with the blood parameter upgrade, but is configured to interface to an otherwise monitor incompatible multiple wavelength sensor. The blood parameter upgrade 410 is described in further detail with respect to FIG. 5, below. The adaptive sensor 610 and the adapter cable 650 are described in further detail with respect to FIGS. 6A–C, below.

FIG. 5 illustrates one embodiment of an upgraded pulse oximetry monitor 500. The monitor 500 has drivers 510, a sensor front-end 520, a signal processor 530, a display 540 and a sampling controller 550, all configured for a conventional pulse oximetry sensor 110 (FIG. 1). In particular, a drive signal 512 is physically and electrically configured to drive a red and an IR sensor emitter 120 (FIG. 1), and the sensor front-end 520 is physically and electrically configured to receive a sensor signal 522 from a detector 130 (FIG. 1).

As shown in FIG. 5, the monitor 500 has software that is upgraded to drive and process signals from a multiple wavelength sensor 610, 660 (FIG. 4) either directly or through an adapter cable 650 (FIG. 4). In one embodiment, a sampling software modification 560 enables the sampling controller 550 to encode the drive signal 512 to provide multiple wavelength control, as described below. A signal processing software modification 570 enables the signal processor 530 to demodulate a multiple wavelength detector signal 522 and to derive blood parameters from a tissue site accordingly. The sampling software modification 560 is described in detail with respect to FIGS. 6–11, below. In one embodiment, the signal processing software modification 570 implements a multiple wavelength demodulation function, such as described in U.S. Pat. No. 6,229,856 entitled “Method and Apparatus for Demodulating Signals in a Pulse Oximetry System,” assigned to Masimo Corporation, Irvine, Calif. and incorporated by reference herein.

FIGS. 6A–C illustrate various embodiments of a blood parameter measurement system 400 utilizing an upgraded pulse oximetry monitor 500. FIG. 6A illustrates a monitor 500 connected to an adaptive multiple wavelength sensor 610. The sensor 610 has emitters 620, at least one detector 630 and a wavelength controller 700. The emitters 620 are capable of illuminating a tissue site with multiple wavelengths. The detector 630 receives multiple wavelengths after transmission through or reflection from the tissue site and provides a corresponding modulated sensor signal output 522. The wavelength controller 700 advantageously interfaces to a conventional driver 510 configured to provide a drive signal output 512 to red and IR LEDs 210, 220 (FIGS. 2A–C), as described above. The driver 510 generates an encoded drive signal 512 according to the sampling software modification 560 (FIG. 5), described above. The wavelength controller 700 decodes the drive signal 512 and enables the emitters 620 accordingly, as described in further detail with respect to FIGS. 7–11, below.

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FIG. 6B illustrates a monitor 500 connected to an adapter cable 650. Advantageously, the adapter cable 650 functions as an interface between an upgraded monitor 500 and an otherwise incompatible multiple wavelength sensor 660. The adapter cable 650 has a wavelength controller 700 that functions in a manner similar to that described with respect to FIG. 6A, above. In particular, the wavelength controller 700 decodes the drive signal 512 and provides corresponding multiple emitter drive signals 652 to the sensor emitters 660.

FIG. 6C illustrates a monitor 500 connected to an adaptive multiple wavelength sensor 610 incorporating a multiple emitter component 690. In one embodiment, the emitter component 690 has multiple emitters 620 and a wavelength controller 700 mounted on an encapsulated carrier. Advantageously, the emitter component 690 may be configured to substitute for or replace a dual LED component within a conventional pulse oximeter sensor so as to convert a pulse oximeter sensor into an adaptive multiple wavelength sensor without the tooling and manufacturing overhead of a unique sensor assembly. In a particularly advantageous embodiment, the wavelength controller 700 is configured such that the adaptive multiple wavelength sensor 610 is backward compatible with monitors that do not have the blood parameter upgrade 410. For example, if the wavelength controller 700 is unable to detect an upgrade encoded pattern in the drive signal 512, the wavelength controller 700 defaults to routing the drive signal 512 to a pair of LEDs having conventional wavelengths and a conventional configuration, as described with respect to FIGS. 2A–C, above. In this manner, a common sensor could be used for either conventional two wavelength pulse oximetry or for expanded multiple wavelength blood parameter measurement capability.

The sensors 610, 660 described with respect to FIGS. 6A–C, above, may have multiple detectors 630 that are enabled by the wavelength controller 700 in conjunction with particular emitters or groups of emitters 620. In this manner, the effective detector bandwidth may be advantageously increased to accommodate the emitter wavelengths. Multiple detector sensor circuits are described with respect to FIGS. 10A–B, below.

FIG. 7 illustrates a wavelength controller 700 having a drive signal input 701, a power supply 710, a sync detector 720, a sensor control 730 and sensor control output 702. The drive signal input 701 is configured to receive the monitor drive signal 512 (FIG. 5). The power supply 710 supplies DC power 712 to the remainder of the wavelength controller 700 and may derive power from any number of input sources, such as a battery, an external AC or DC supply 705, or the drive signal input 701. The sync detector 720 decodes the drive signal input 701 to determine the occurrence of a sync pattern in the drive signal waveform and provides a sync output 722 that indicates a sync event to the sensor control 730 accordingly. A sync pattern may be encoded as a unique pulse pattern on the drive signal 512 (FIG. 5) by the sampling software modification 560 (FIG. 5). The sensor control 730 utilizes the sync output 722 to synchronize emitter selection with the upgrade software 410 (FIG. 4), so that the upgrade software 410 (FIG. 4) can properly identify and process detector response at each wavelength, as described below. The sensor control 730 is responsive to drive current pulses on the drive signal input 701 so as to sequentially select particular sensor emitters 620 (FIGS. 6A–C). The sensor control output 702 routes the drive signal 512 (FIG. 5) from the drive signal input 701 to the selected emitters 620 (FIGS. 6A–C).

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As shown in FIG. 7, the wavelength controller 700 may also have a command decoder 740 and a transmitter 750. The command decoder 740 determines the occurrence of a command pattern in the drive signal waveform and provides a command output 742, 744 to the sensor control 730 and/or the transmitter 744 in response. Commands may be encoded as one or more unique pulse patterns on the drive signal 512 (FIG. 5) by the sampling software modification 560 (FIG. 5). A command, for example, may program the sensor control 730 for a particular emitter enabling sequence or instruct the transmitter 750 to send. The transmitter 750 is configured to send sensor status or other sensor information to the monitor 500 (FIG. 5) when the drive signal 512 (FIG. 5) is off. To receive such information, the monitor 500 (FIG. 5) would have a corresponding receiver (not shown) sharing the drive conductors as inputs.

FIG. 8A illustrates one wavelength controller 700 embodiment having a drive signal input 701, an AC-DC converter 710, a sync detector 720, an output multiplexer 740 and sensor control outputs 702. A drive signal 512 (FIG. 5) is provided on the drive control input 701, as described with respect to FIG. 7, above. The drive signal input 701 may have, for example, two conductors to accommodate a bipolar drive signal, such as described with respect to FIG. 3B, above, or it may have an additional common conductor 803 to accommodate two unipolar drive signals, such as described with respect to FIG. 3C, above. The converter 710 pulls some current from the drive signal input 701 so as to provide DC power 712 to the controller electronics. The sync detector 720 decodes the drive signal input 701 and provides a sync output 722, as described with respect to FIG. 7, above. The output multiplexer 730 routes the drive signal input 701 to a selected pair of sensor control outputs 702. Each pair of sensor control outputs 702 is in communication with a pair of emitters 620 (FIGS. 6A-C), such as described with respect to FIGS. 9A-B, below.

In operation, the sync output 722 initializes the output multiplexer 740 so that a first pair of sensor control outputs 702 is selected, which selects a predetermined pair of emitters 620 (FIGS. 6A-C). Individual ones of a selected emitter pair are then enabled according to the drive current waveform, as described with respect to FIGS. 3A-C, above. The drive current waveform on the drive signal input 701 also causes the output multiplexer 740 to enable other pairs of drive outputs 702, selecting other emitter pairs in a predetermined sequence.

FIG. 8B illustrates a wavelength control element 800 that functions in combination with switches 1010 (FIGS. 10A-B) as a wavelength controller 700 (FIG. 7) embodiment, as described above. The wavelength control element 800 has an input 701, an AC-DC converter 710 and a sync detector 930 that function as described with respect to FIG. 8A, above. The wavelength control element 800 also has a switch control 830 that functions in combination with switches 1010 (FIGS. 10A-B) to route the drive signal input 701 to selected pairs of emitters 620 (FIGS. 6A-C), such as described with respect to FIGS. 10A-B, below. In particular, each switch control output 805 actuates one or more switches to connect or disconnect a selected emitter pair to the drive signal 512 (FIG. 5).

In operation, the sync output 722 initializes the switch control 830 so that a first switch control output 805 is selected, which actuates a switch or switches that connect a predetermined pair of emitters 620 (FIGS. 6A-C) to the drive signal 512 (FIG. 5). Individual ones of a selected emitter pair are then enabled according to the drive current waveform, as described with respect to FIGS. 3A-C, above.

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The drive current waveform on the drive signal input 701 also causes the switch control 830 to enable other switch control outputs 805, selecting other emitter pairs in a predetermined sequence.

FIGS. 9A-B illustrate back-to-back LED and common anode LED embodiments of a sensor circuit 900, 950 respectively, each having LEDs 620, a photodiode 630 and a wavelength controller 700. The drive signal inputs 701 connect to the drivers 510 (FIG. 5) so as to receive a drive signal 512 (FIG. 5). Photodiode pinouts 901 connect to the sensor front-end 520 (FIG. 5) so as to provide a detector signal 522 (FIG. 5). The wavelength controller 700 selects a pair of LEDs 620 in response to the drive signal 512 (FIG. 5) on the drive signal input 701, communicating the drive signal 512 (FIG. 5) to the selected LEDs 620. These elements may be incorporated into an adaptive sensor 610 (FIGS. 6A, C) or in a combination adapter cable 650 (FIG. 6B) and multiple wavelength sensor 660 (FIG. 6B). With respect to FIG. 9A, a bipolar drive current, having characteristics similar to those described with respect to FIG. 3B, above, enables individual LEDs of a selected back-to-back LED pair. With respect to FIG. 9B, a pair of unipolar drive currents, having characteristics similar to those described with respect to FIG. 3C, above, enables individual LEDs of a selected common anode LED pair. A similar sensor circuit would accommodate common cathode LEDs. The sequence and timing of LED selection is described in detail with respect to FIGS. 11A-B, below.

FIGS. 10A-B illustrate back-to-back LED and common anode LED embodiments of a sensor circuit 1000, 1050, respectively, each having LEDs 620, photodiodes 630 and a wavelength control element 800. A drive signal input 701 connects to the drivers 510 (FIG. 5) so as to receive a drive signal 512 (FIG. 5). Photodiode pinouts 1001 connect to the sensor front-end 520 (FIG. 5) so as to provide a detector signal 522 (FIG. 5). The wavelength control element 800 selects a pair of LEDs 620 in response to the drive signal 512 (FIG. 5) on the drive signal input 701. Each LED pair is selectable by the switches 1010, which either connect an LED pair to the drive signal input 701 or isolate an LED pair from the drive signal input 701. In a multiple photodiode embodiment, the wavelength control element 800 also selects a corresponding photodiode 630. Each photodiode 630 is selectable by the switches 1010, which either connect it to, or isolate it from, the photodiode pinouts 1001. Multiple photodiodes 630 advantageously allow optical radiation detection over a broader range of wavelengths than practical from a single photodiode, due to the bandwidth limitations of such components. The switches 1010 are actuated so as to select a photodiode 630 having an operating range that corresponds to the wavelength of the selected LEDs 620.

These elements may be incorporated into an adaptive sensor 610 (FIGS. 6A, C) or in a combination adapter cable 650 (FIG. 6B) and multiple wavelength sensor 660 (FIG. 6B). With respect to FIG. 10A, a bipolar drive current, having characteristics similar to those described with respect to FIG. 3B, above, enables individual LEDs of a selected back-to-back pair. With respect to FIG. 10B, a pair of unipolar drive currents, having characteristics similar to those described with respect to FIG. 3C, above, enables individual LEDs of a selected common anode pair. A similar sensor circuit would accommodate common cathode LEDs. The switches 1010 may be electromechanical or electronic devices, such as field-effect transistors (FETs). The sequence and timing of LED selection is described in detail with respect to FIGS. 11A-B, below.

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FIGS. 11A–B illustrate multiple wavelength control timing, as generated by a sampling controller 550 (FIG. 5), according to a sampling software upgrade 560 (FIG. 5). As shown in FIG. 11A, the control timing 1100 includes a header interval 1110 and an emitter drive interval 1130. The header 1110 may include one or more of sync, command, transmission and idle time periods. During a sync time period, an encoded drive waveform is generated for the sync detector 720 (FIG. 7), as described above. During a command time period, an encoded drive waveform is generated for the command decoder 740 (FIG. 7), as described above. During the transmission time period, the drivers 510 (FIG. 5) have a high impedance output, for example, so that the transmitter 750 (FIG. 7) may send on the same conductors as the drive signal 512 (FIG. 5), as described above. The drive interval 1130 may include multiple drive current pulses and interleaved dark periods, as described with respect to FIGS. 3A–C, above.

As shown in FIG. 11B, one embodiment of the control timing 1100 includes a sync period 1111 and an idle period 1112 in the header interval 1110 and a sequence of LED enable periods 1131–1135 interleaved with dark periods 1134 during the emitter drive interval 1130. During the sync period 1110 the sampling controller 550 (FIG. 5) and signal processor 530 (FIG. 5) in the monitor are synchronized with the wavelength controller in the sensor. In this manner, the signal processor can determine which wavelength response corresponds to the detector signal 522 (FIG. 5) at any particular time. During the LED enable periods 1131–1135, the drivers 510 (FIG. 5) generate drive current that is routed by the wavelength controller to the LEDs in a predetermined sequence, as described with respect to FIGS. 7–10, above.

The LED enable sequence 1131, 1133, 1135 can be any number of patterns. For example, for a three-wavelength sensor, the LED enable pattern can be 1, 2, 3, 1, 2, 3, . . . as shown, where the numbers correspond to individual LEDs, such as an IR LED and two red LEDs. As another example, the LED enable pattern can be 1, 2, 1, 3, 1, 2, 1, 3, . . . Further, the duration or duty cycle of LED enable periods can vary. For example, for a three-wavelength sensor, the duration for each LED enable period and each dark period can be the same, such that each LED has a 16.7% duty cycle. As another example, the IR LED can have a 28.6% duty cycle and the red LEDs can each have a 14.3% duty cycle, to name just a few timing variations.

A blood parameter measurement system has been disclosed in detail in connection with various embodiments. These embodiments are disclosed by way of examples only and are not to limit the scope of the claims that follow. One of ordinary skill in the art will appreciate many variations and modifications.

What is claimed is:

1. A blood parameter measurement system comprising:
 - a monitor configured to provide an oxygen saturation measurement based upon the absorption of two wavelengths of optical radiation by a tissue site;
 - a software upgrade installable in said monitor so as to enable said monitor to operate in conjunction with a multiple wavelength sensor; and
 - a wavelength controller adapted to said upgrade so as to drive said sensor, wherein said upgrade comprises:
 - sampling software providing a drive waveform for said sensor; and
 - signal processing software adapted to demodulate a multiplexed signal from said sensor.

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2. The blood parameter measurement system according to claim 1 wherein said drive waveform comprises:

- a header interval that controls said wavelength controller; and
- an emitter drive interval that enables drive current to said sensor.

3. The blood parameter measurement system according to claim 2 wherein said header interval comprises a sync period decodable by said wavelength controller so as to synchronize said wavelength controller and said upgrade.

4. The blood parameter measurement system according to claim 2 wherein said header interval comprises a command interval decodable by said wavelength controller so as to allow said upgrade to command said wavelength controller.

5. A blood parameter measurement system comprising:
 - a monitor configured to provide an oxygen saturation measurement based upon the absorption of two wavelengths of optical radiation by a tissue site;
 - a software upgrade installable in said monitor so as to enable said monitor to operate in conjunction with a multiple wavelength sensor; and
 - a wavelength controller adapted to said upgrade so as to drive said sensor, wherein said wavelength controller is located in an adapter cable, and said adapter cable provides an interface between the sensor port of said monitor and said sensor.

6. A blood parameter measurement system comprising:
 - a monitor configured to provide an oxygen saturation measurement based upon the absorption of two wavelengths of optical radiation by a tissue site;
 - a software upgrade installable in said monitor so as to enable said monitor to operate in conjunction with a multiple wavelength sensor; and
 - a wavelength controller adapted to said upgrade so as to drive said sensor, wherein said wavelength controller is integrated into said sensor.

7. The blood parameter measurement system according to claim 6 wherein said wavelength controller is co-located with multiple LEDs within an emitter component, said emitter component adapted to substitute for a two-wavelength emitter component within a pulse oximetry sensor.

8. A blood parameter measurement system comprising:
 - a monitor configured to provide an oxygen saturation measurement based upon the absorption of two wavelengths of optical radiation by a tissue site;
 - a software upgrade installable in said monitor so as to enable said monitor to operate in conjunction with a multiple wavelength sensor; and
 - a wavelength controller adapted to said upgrade so as to drive said sensor, wherein said wavelength controller comprises:
 - a sensor control configured to route a drive signal to a select one of a plurality of sensor emitters; and
 - a sync detector adapted to decode a sync interval on said drive signal so as to synchronize the operations of said software upgrade and said wavelength controller.

9. The blood parameter measurement system according to claim 8 wherein said wavelength controller further comprises a command decoder adapted to decode a command interval on said drive signal so as to accept commands from said software upgrade.

10. The blood parameter measurement system according to claim 8 wherein said wavelength controller further comprises a transmitter configured to communicate sensor information to said monitor on conductors that communicate said drive signal.

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11. The blood parameter measurement system according to claim 8 wherein said sensor control comprises an output multiplexer that routes said drive signal to selected emitters of said sensor.

12. The blood parameter measurement system according to claim 8 wherein said sensor control comprises:
a plurality of switches configured to connect and disconnect said drive signal and emitters of said sensor; and
a switch control configured to actuate select ones of said switches.

13. A blood parameter measurement method comprising the steps of:
communicating a drive, signal from a monitor to a sensor;
synchronizing said sensor with said monitor;
sequentially enabling a plurality of emitters of said sensor; and
communicating a sensor signal from said sensor to said monitor, wherein said synchronizing step comprises the substeps of:
inputting said drive signal to a wavelength controller;
and
decoding a header interval of said drive signal so as to detect a sync event.

14. The blood parameter measurement method according to claim 13 wherein said enabling step comprises the substeps of:
selecting a predetermined first emitter pair of said sensor in response to said sync event;
routing said drive signal to said first emitter pair, and
activating said first emitter pair during a drive interval of said drive signal.

15. The blood parameter measurement method according to claim 14 wherein said enabling step comprises the further substeps of:

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deactivating said first emitter pair;
selecting a predetermined second emitter pair to follow said first emitter pair;
routing said drive signal to said second emitter pair and activating said second emitter pair during a drive interval of said drive signal.

16. A blood parameter measurement system comprising:
a multiple wavelength sensor means for illuminating a tissue site with at least three wavelengths and detecting a corresponding tissue site response;
a software upgrade means for enabling a pulse oximetry monitor to drive said sensor and process a corresponding sensor signal; and
a wavelength controller means for interfacing between said software upgrade means and said multiple wavelength sensor means.

17. The blood parameter measurement system according to claim 16 wherein said software upgrade means comprises:
a sampling controller means for generating an encoded drive signal; and
a signal processing means for demodulating said sensor signal.

18. The blood parameter measurement system according to claim 17 wherein said wavelength controller means comprises a sync decoder means for synchronizing with said software upgrade means in response to said encoded drive signal.

19. The blood parameter measurement system according to claim 16 wherein said wavelength controller means comprises a sensor control means for routing a drive signal from said monitor to a selected one of a plurality of sensor emitters.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION



PATENT NO. : 7,027,849 B2
APPLICATION NO. : 10/719928
DATED : April 11, 2006
INVENTOR(S) : Al-Ali

Page 1 of 1

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

On Title Page

Page 2, column 2 (U.S. Patent Documents), line 14, after “6,658,276” delete “B1” and insert -- B2 --, therefore.

Sheet 3 of 16 (Fig. 3A), Right hand side (Beside Box 330), delete “” and insert --  --, therefore.

Column 3, line 12, delete “ $\epsilon_{i,\lambda}$ ” and insert -- $\epsilon_{i,\lambda}$ --, therefore.

Column 8, line 64, delete “electromechanical” and inset -- electro-mechanical --, therefore.

Column 9, line 43, delete “duty” and insert -- duty --, therefore.

Column 11, line 13, in Claim 13, delete “drive,” and insert -- drive --, therefore.


Column 11, line 29, in Claim 14, delete “pair,” and insert -- pair; --, therefore.

Column 12, line 4, in Claim 15, after “pair” insert -- ; --.

Column 12, line 10, in Claim 16, delete “sfte” and insert -- site --, therefore.

Signed and Sealed this

Tenth Day of July, 2007



JON W. DUDAS
Director of the United States Patent and Trademark Office

EXHIBIT 5



US007764982B2

(12) **United States Patent**
Dalke et al.

(10) **Patent No.:** **US 7,764,982 B2**
(45) **Date of Patent:** **Jul. 27, 2010**

(54) **MULTIPLE WAVELENGTH SENSOR EMITTERS**

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(75) Inventors: **David Dalke**, Irvine, CA (US); **Ammar Al-Ali**, Tustin, CA (US); **Mohamed Diab**, Mission Viejo, CA (US); **Marcelo Lamego**, Rancho Santa Margarita, CA (US); **Robert Smith**, Lake Forest, CA (US)

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 479 days.

(Continued)

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(Continued)

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(22) Filed: **Mar. 1, 2006**

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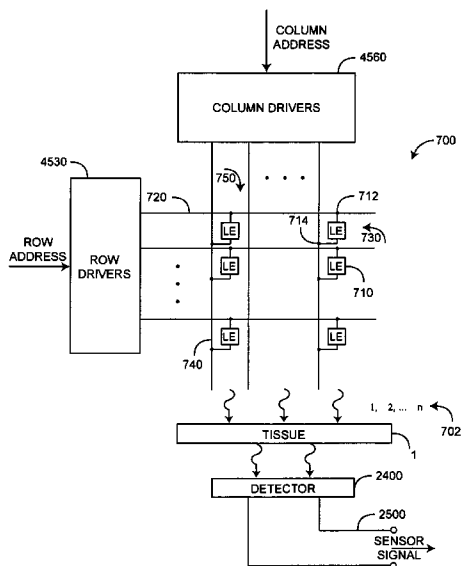
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(57)

ABSTRACT

A physiological sensor has light emitting sources, each activated by addressing at least one row and at least one column of an electrical grid. The light emitting sources are capable of transmitting light of multiple wavelengths and a detector is responsive to the transmitted light after attenuation by body tissue.

22 Claims, 48 Drawing Sheets



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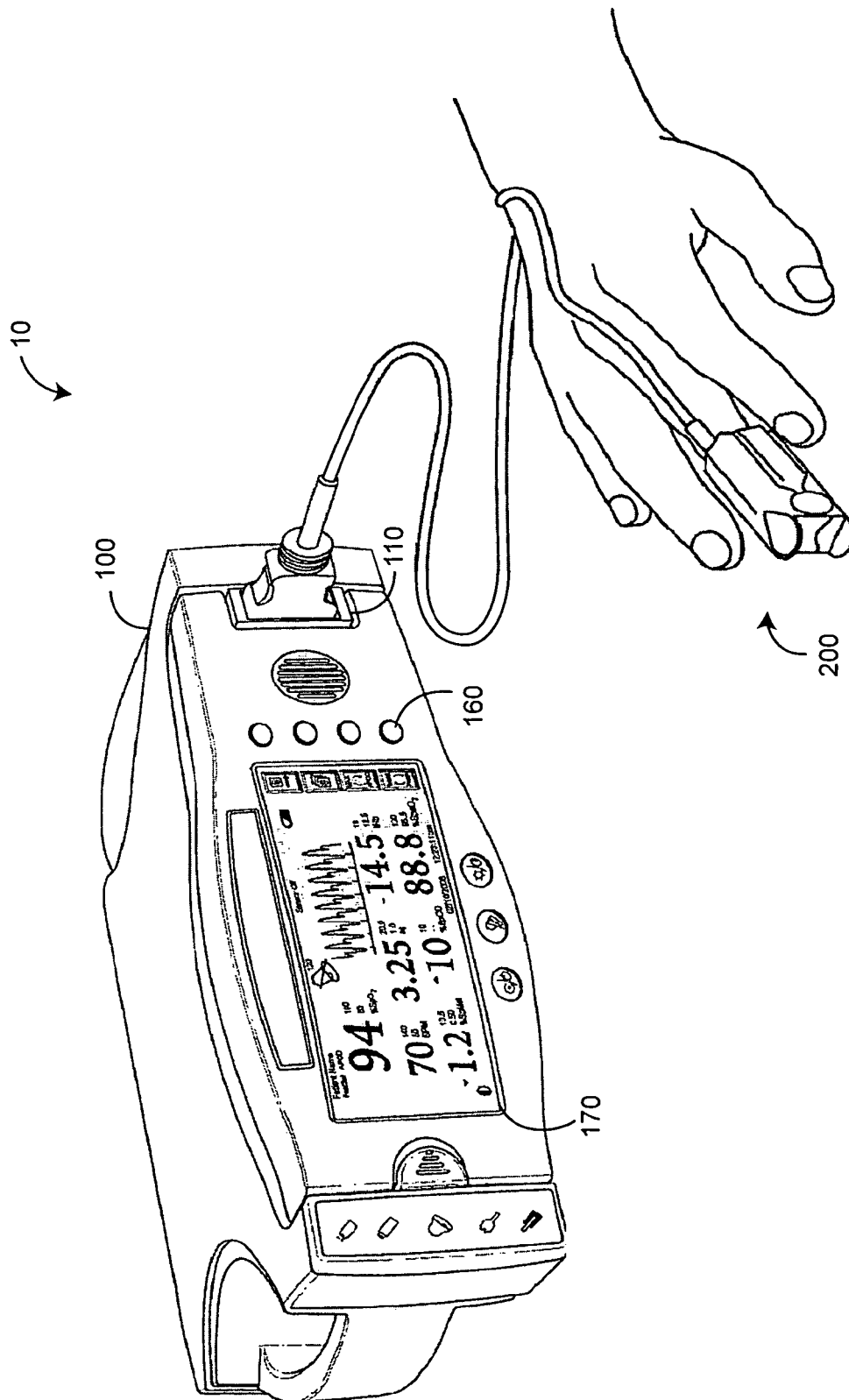


FIG. 1

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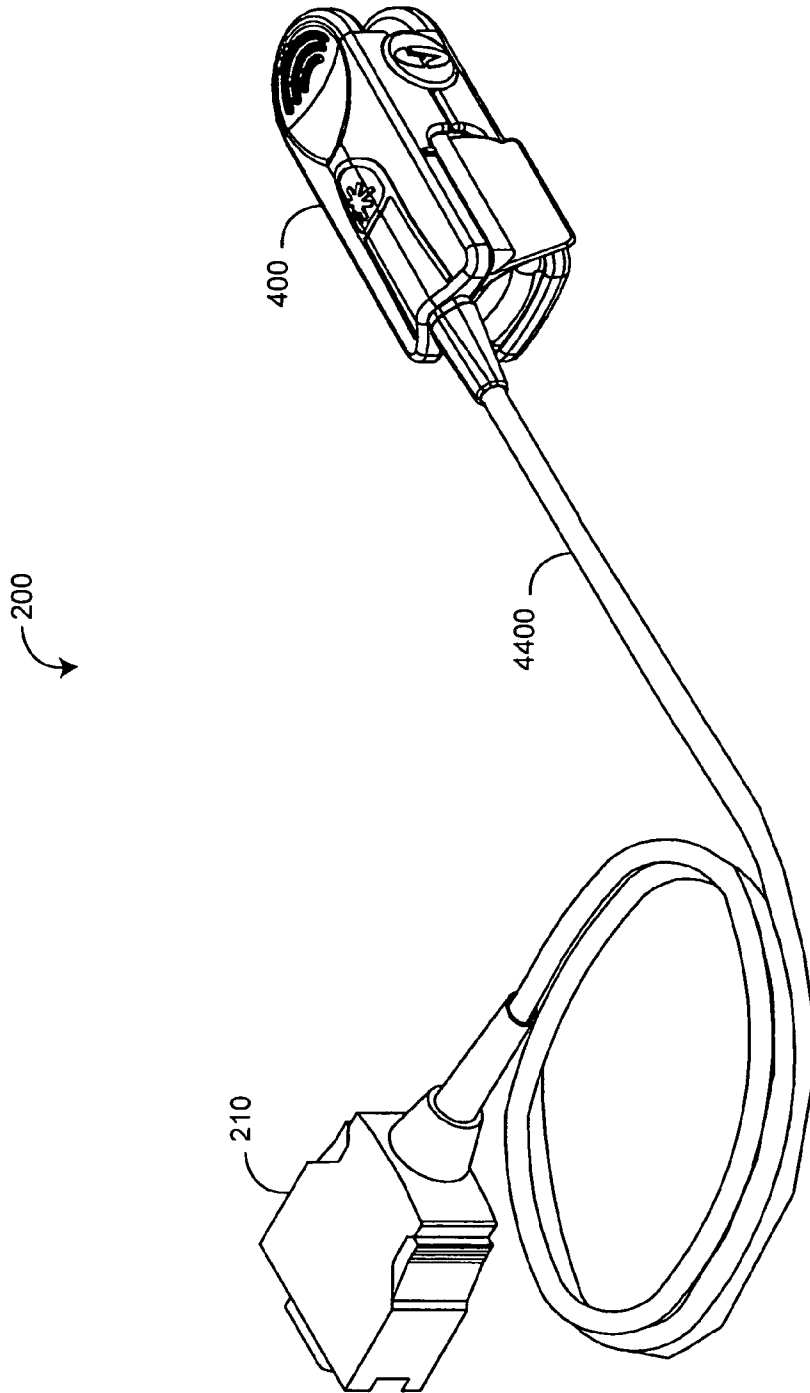


FIG. 2A

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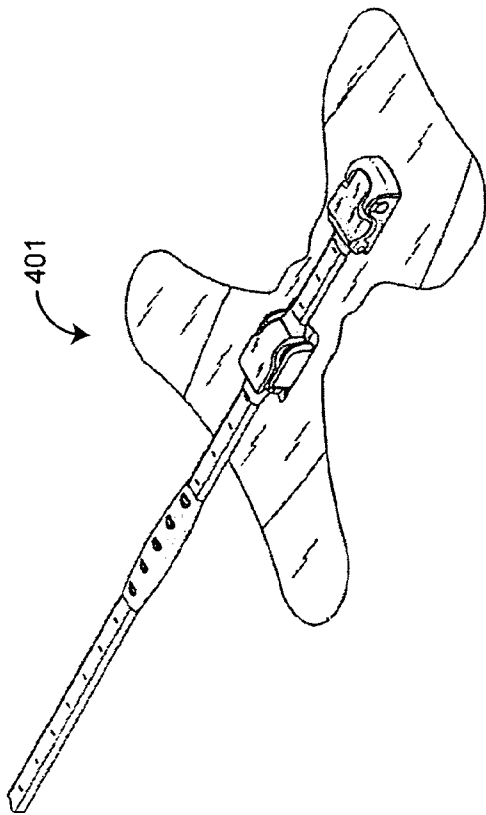


FIG. 2B

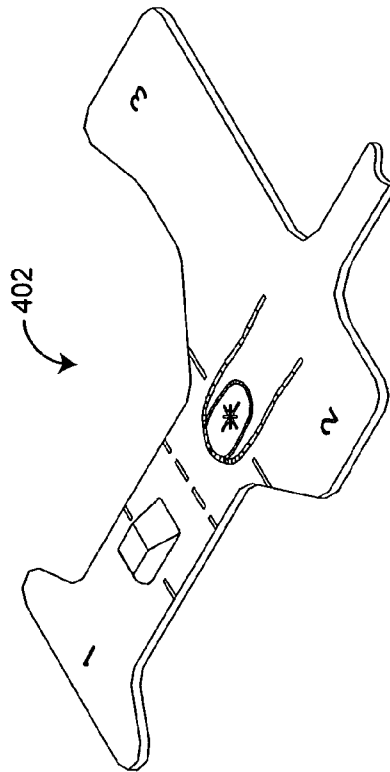


FIG. 2C

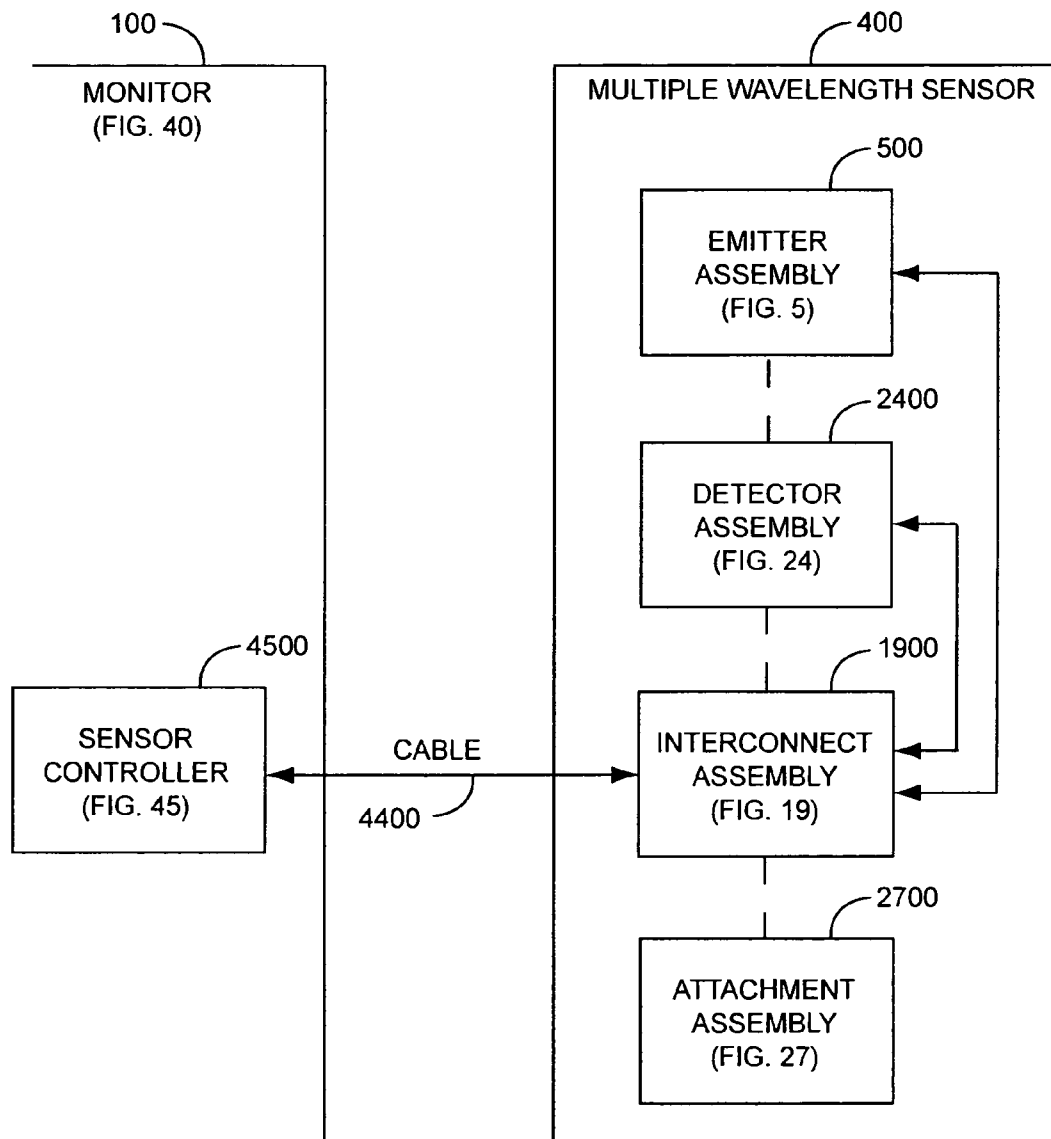


FIG. 3

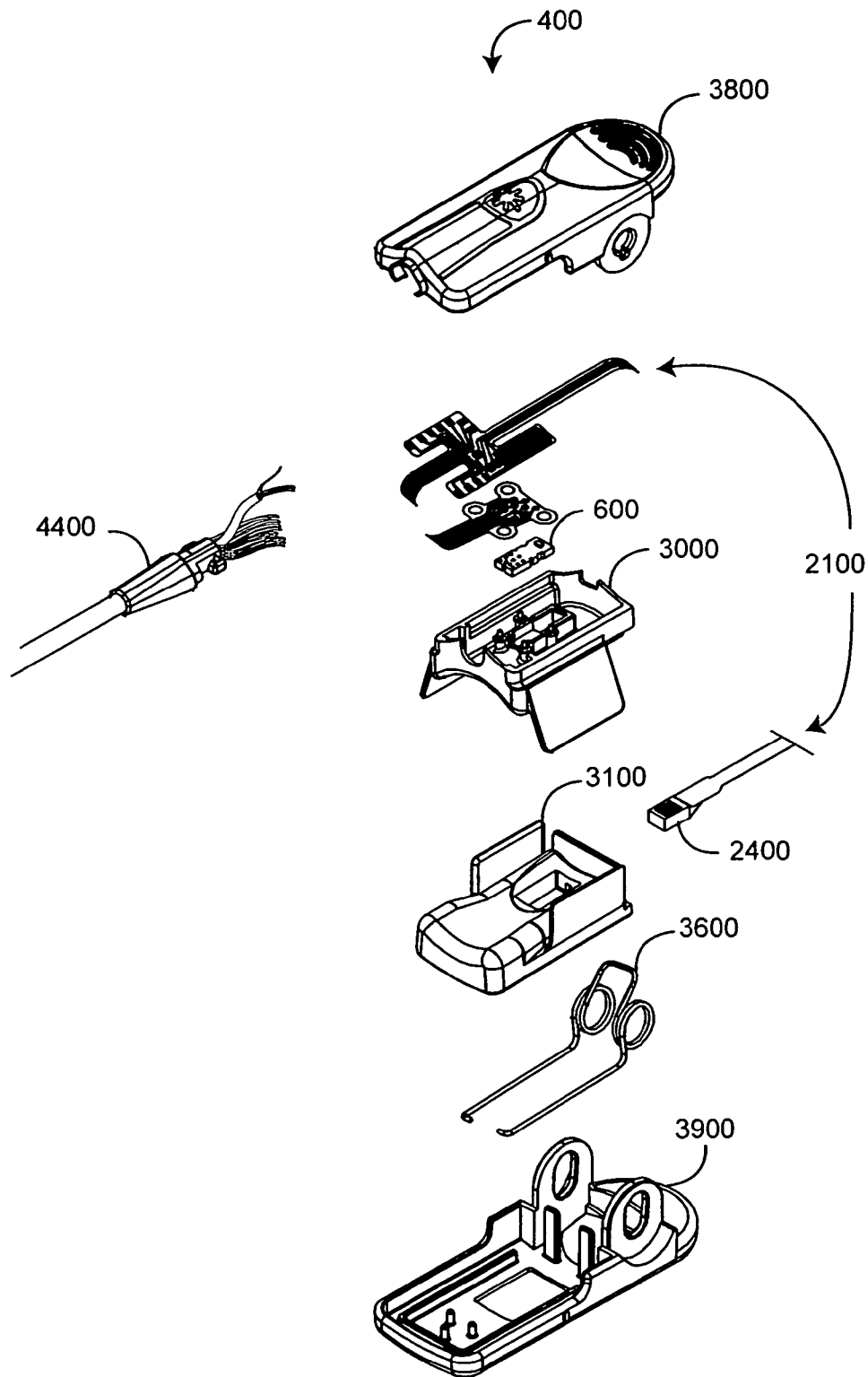


FIG. 4

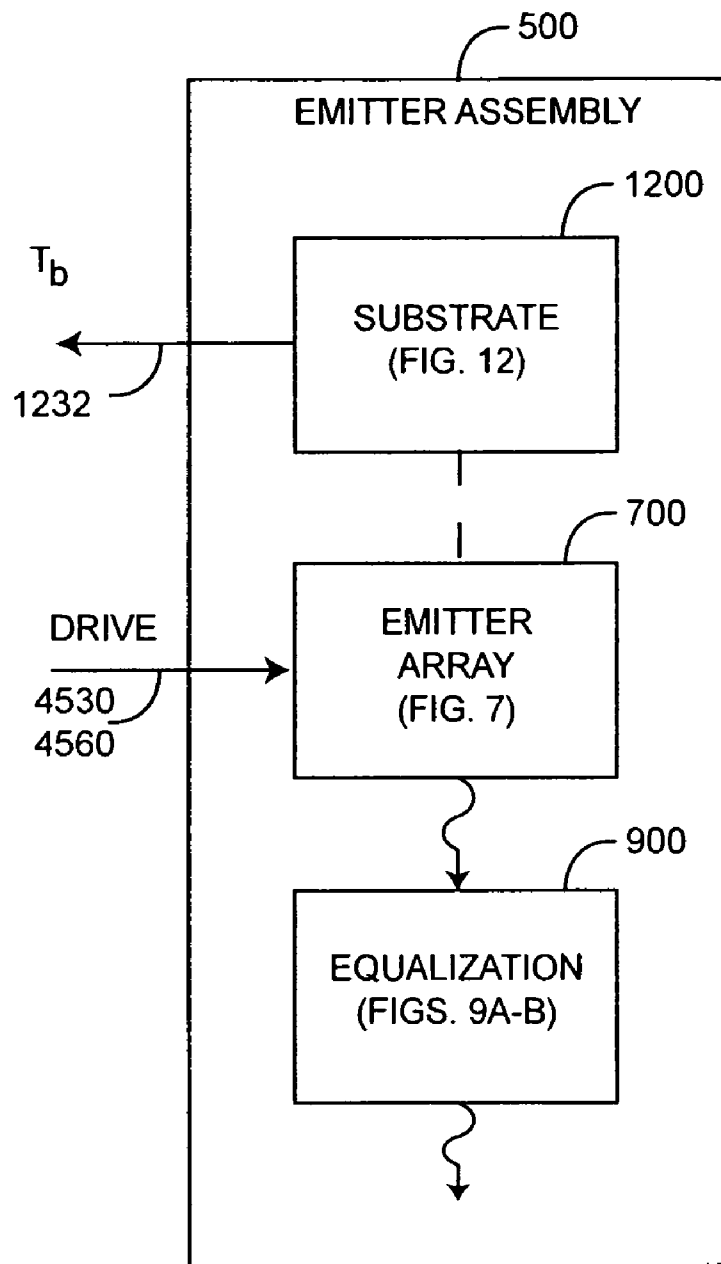


FIG. 5

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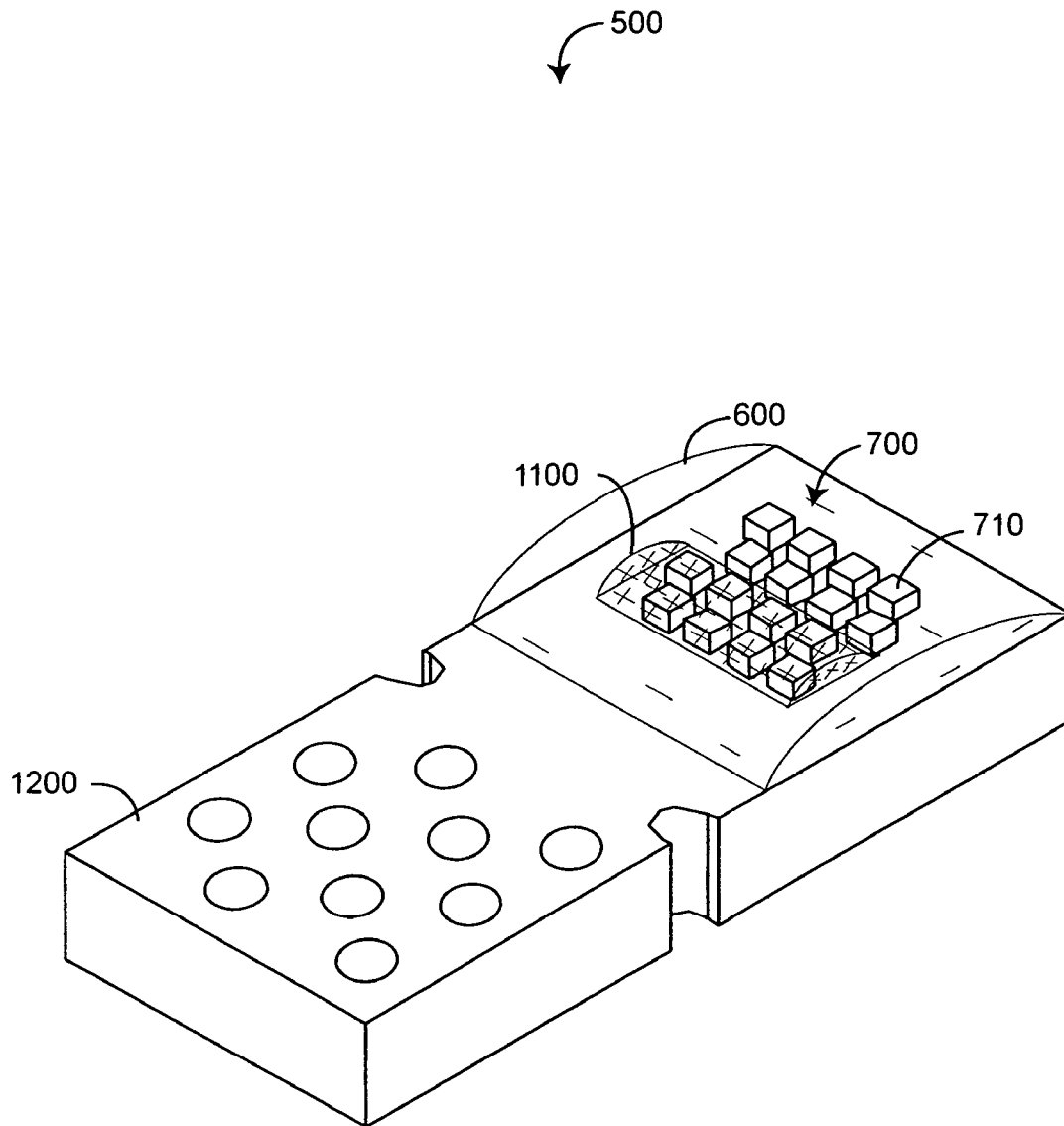


FIG. 6

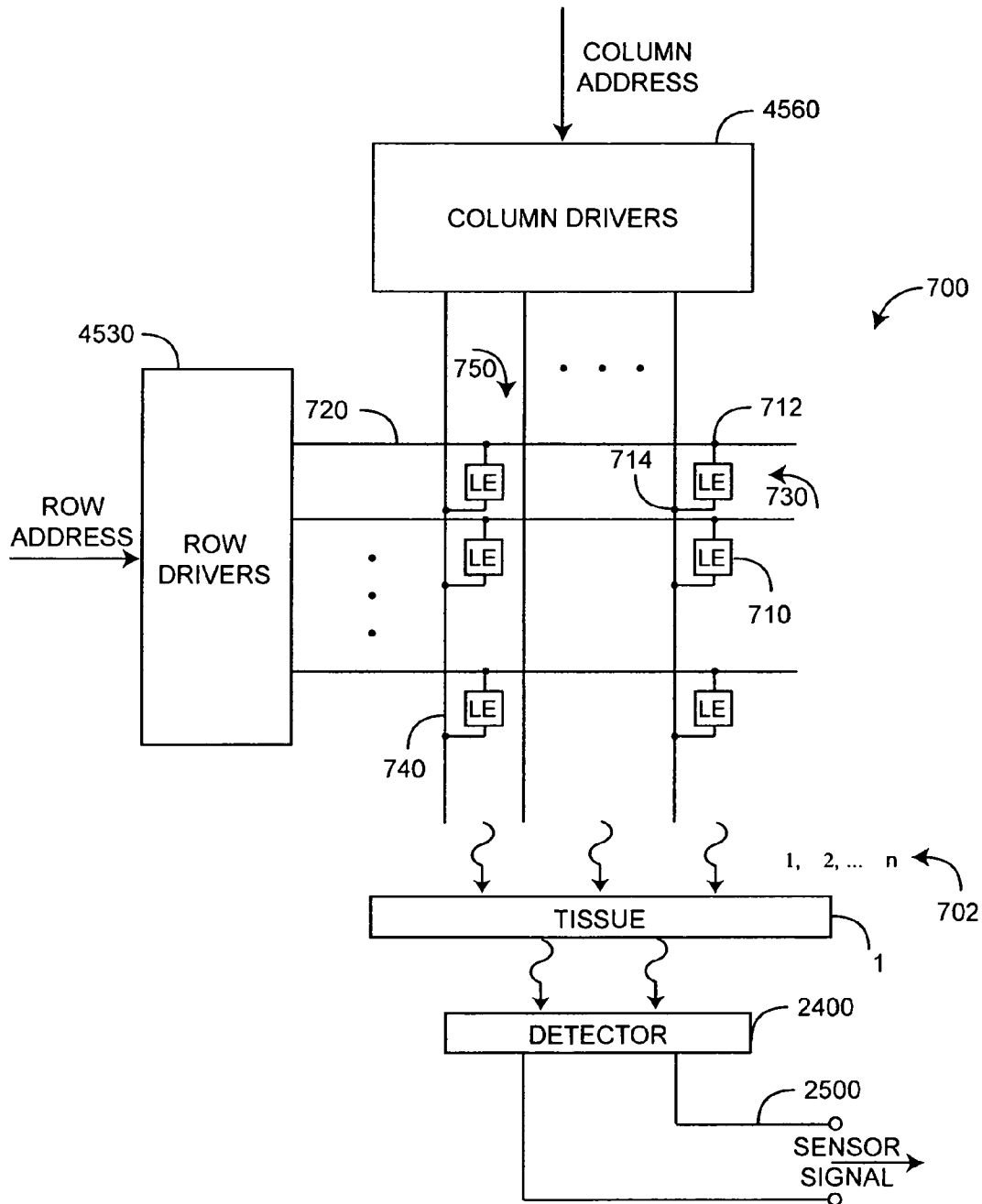


FIG. 7

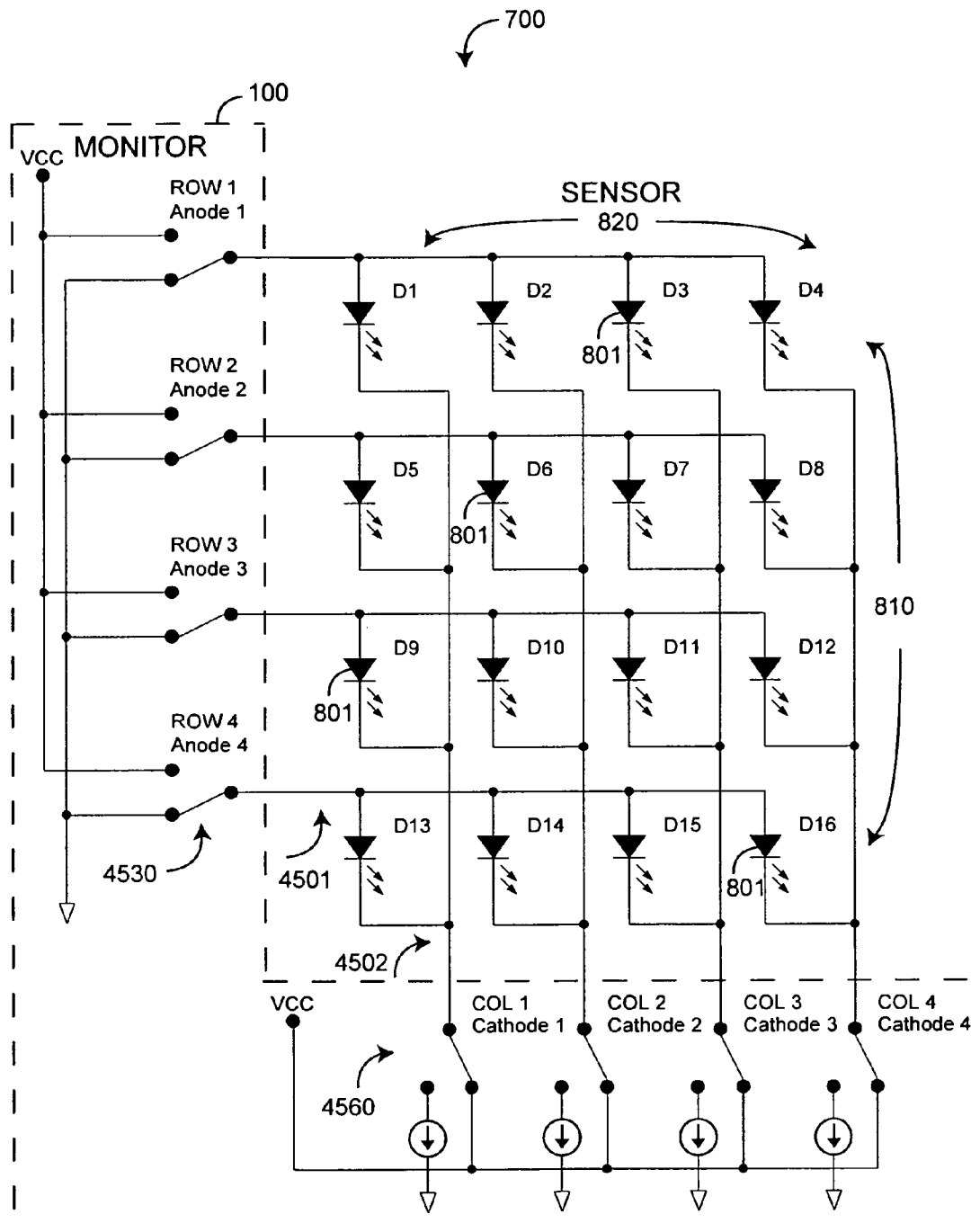


FIG. 8

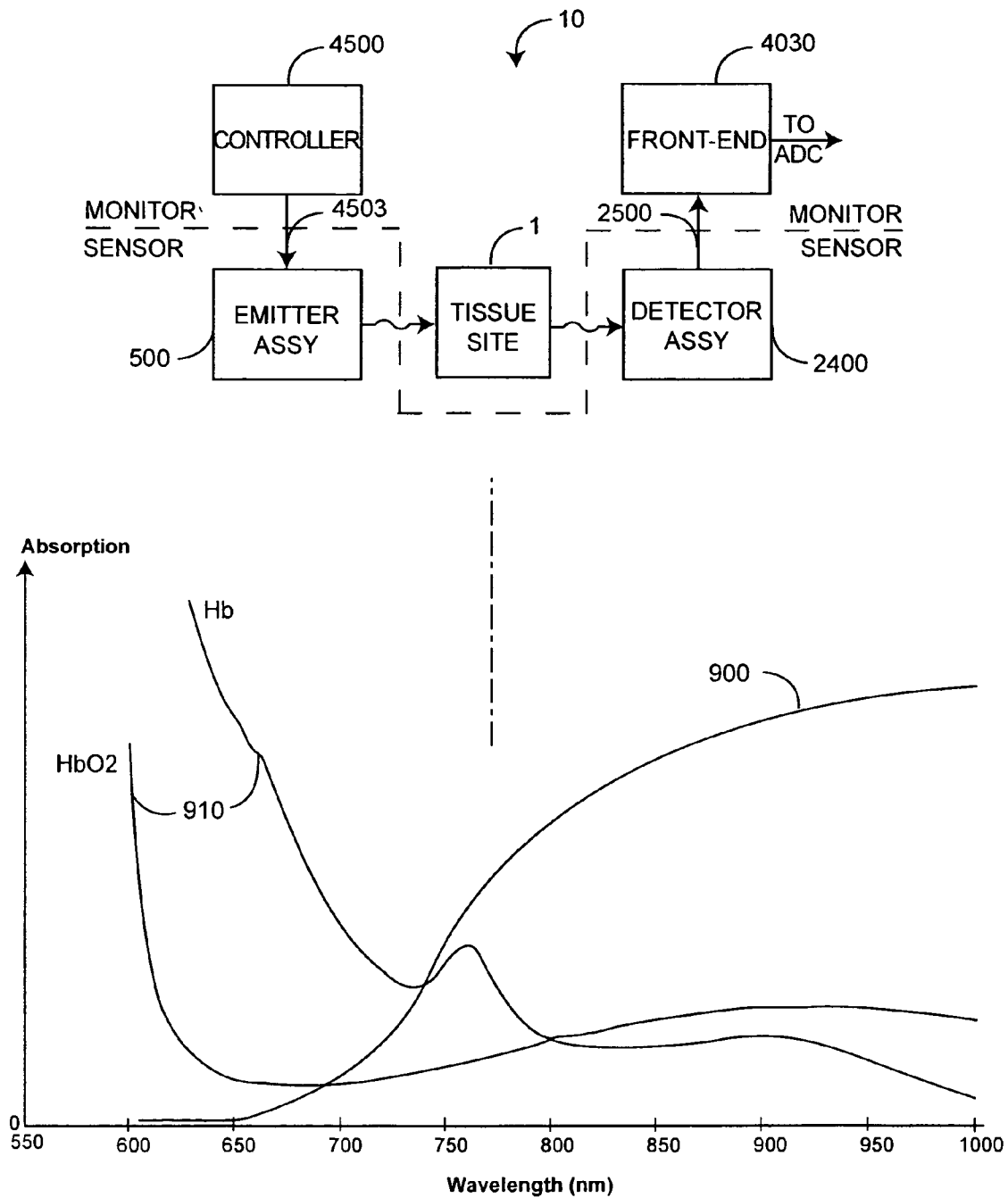


FIG. 9

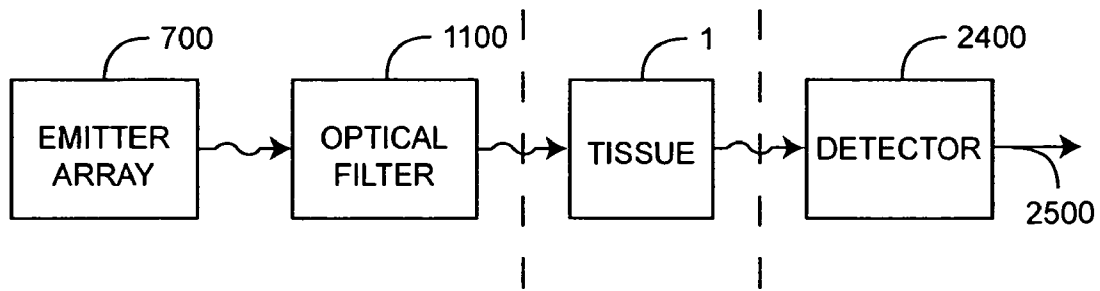


FIG. 10A

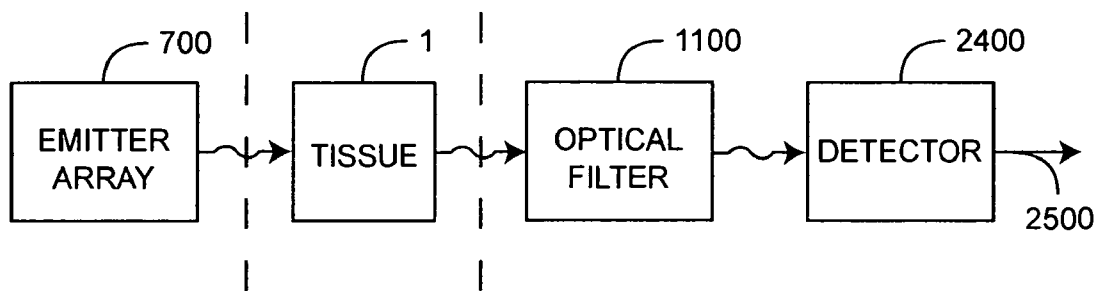


FIG. 10B

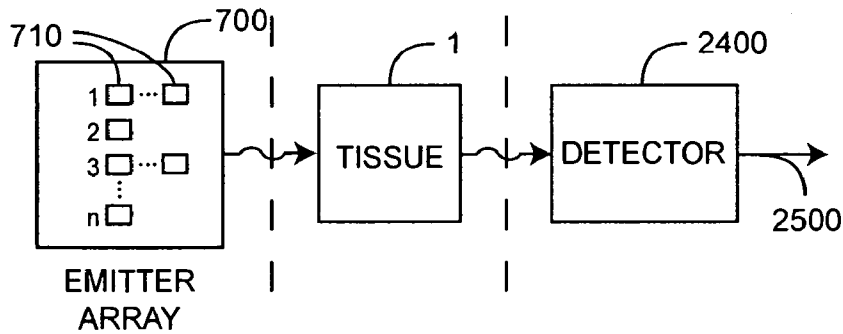


FIG. 10C

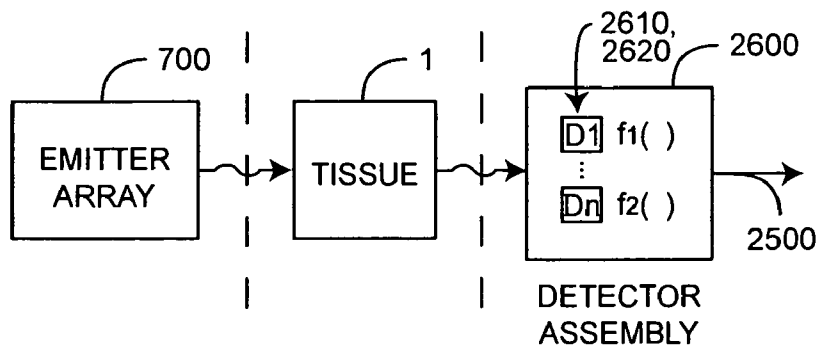


FIG. 10D

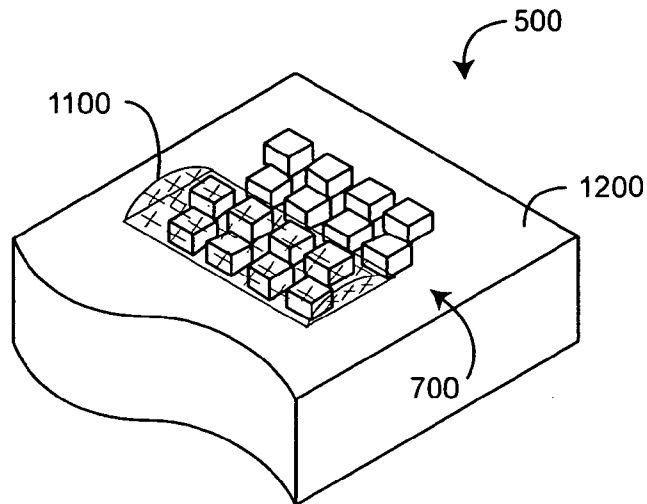


FIG. 11A

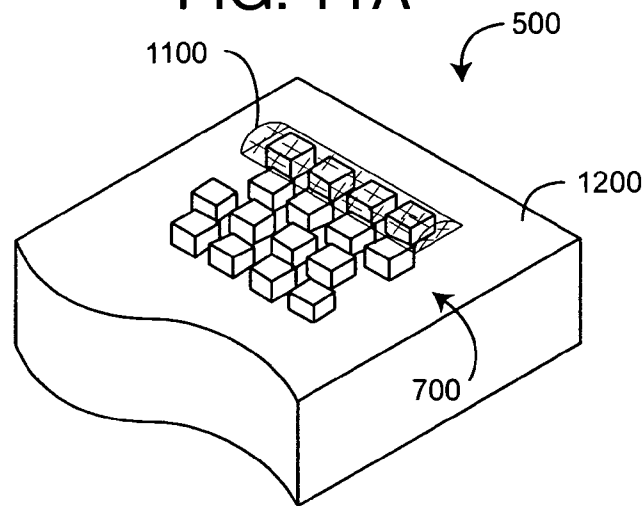


FIG. 11B

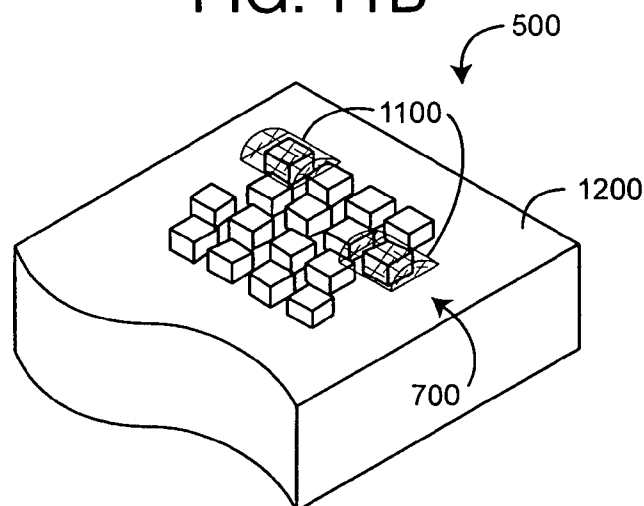


FIG. 11C

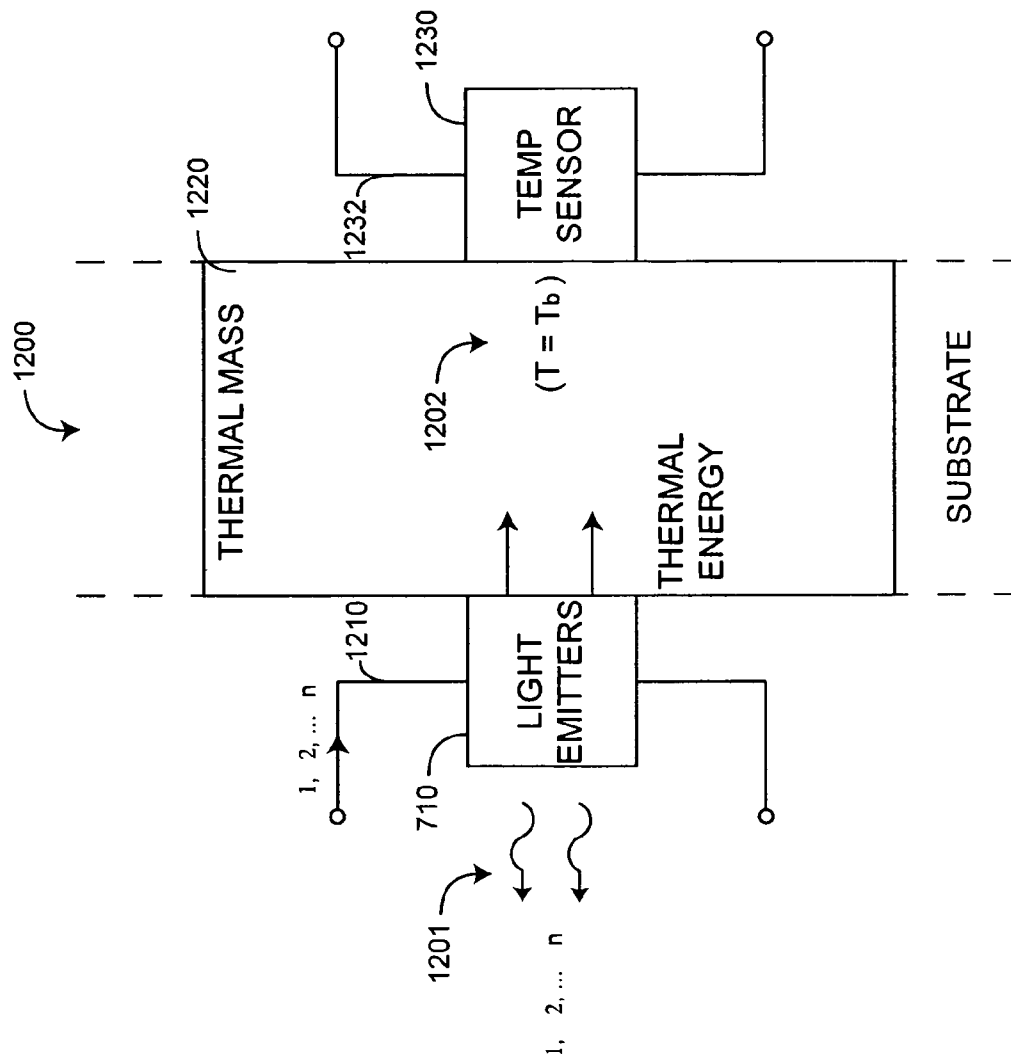


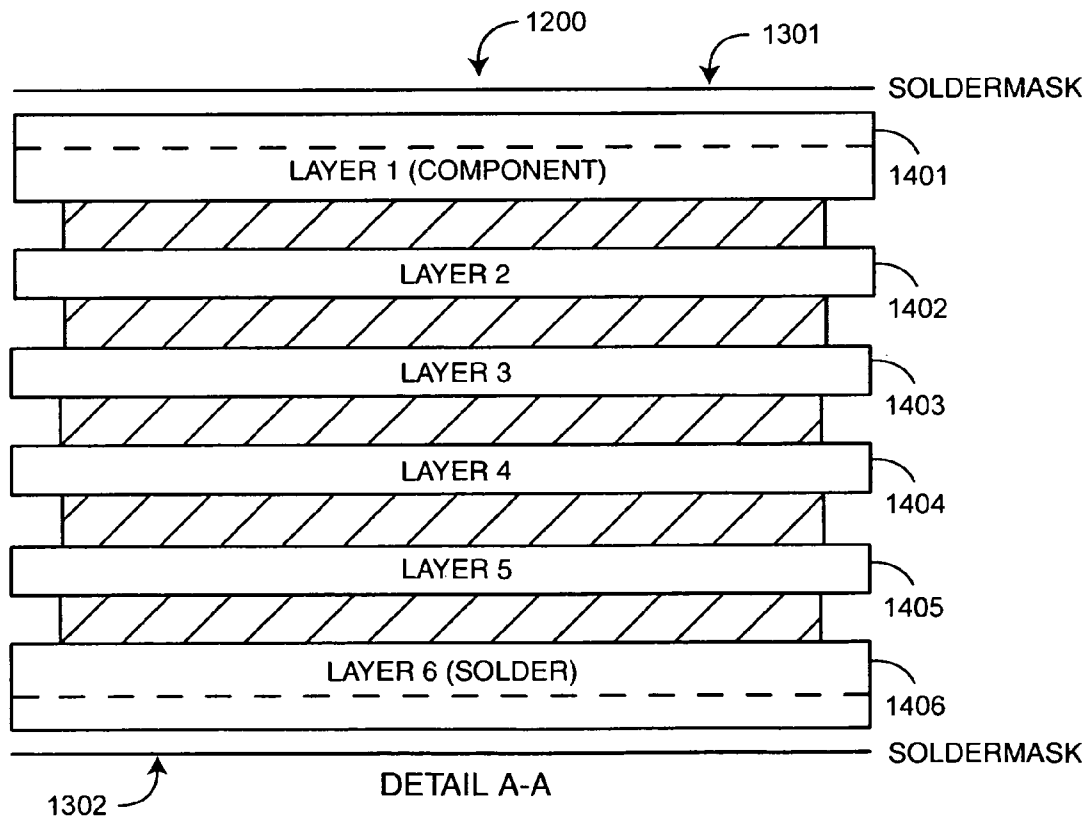
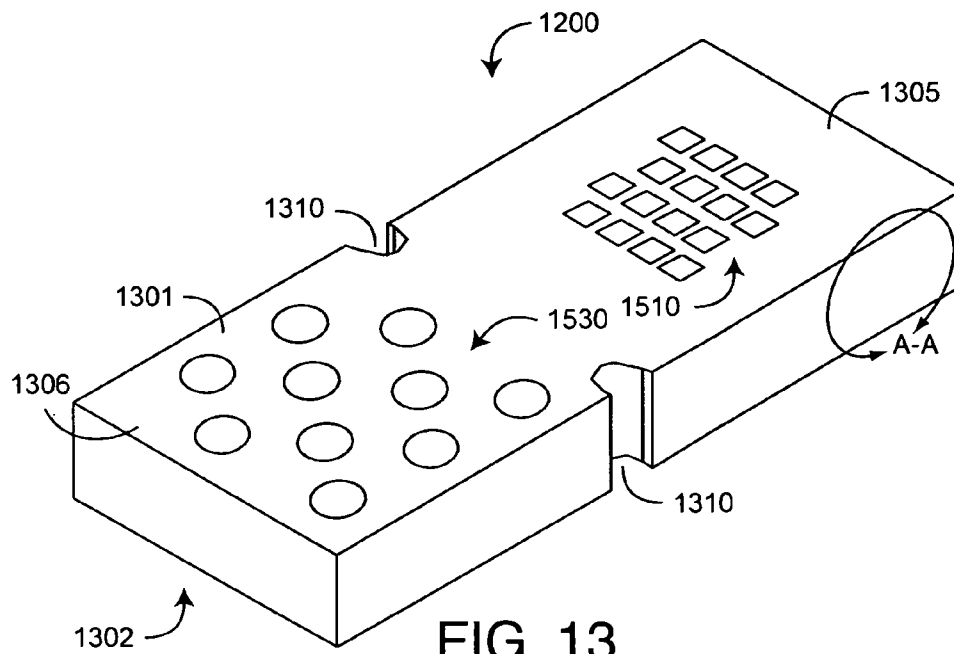
FIG. 12

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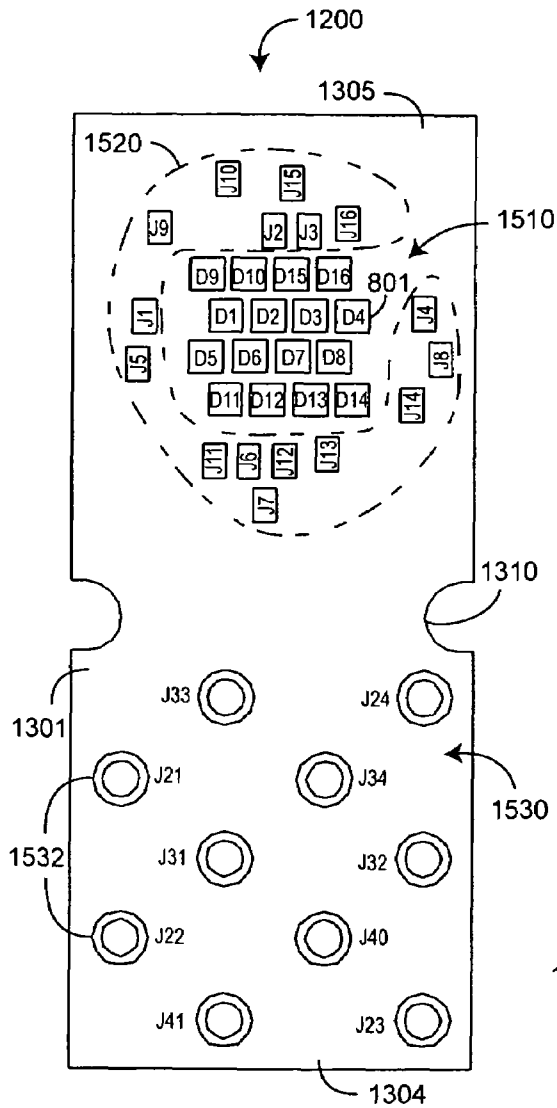


FIG. 15

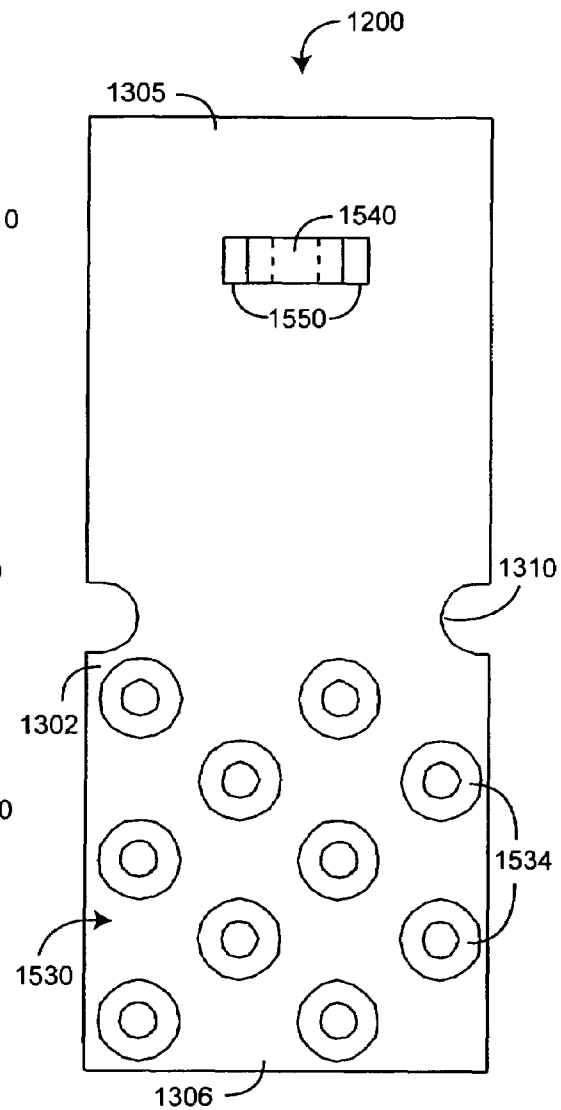
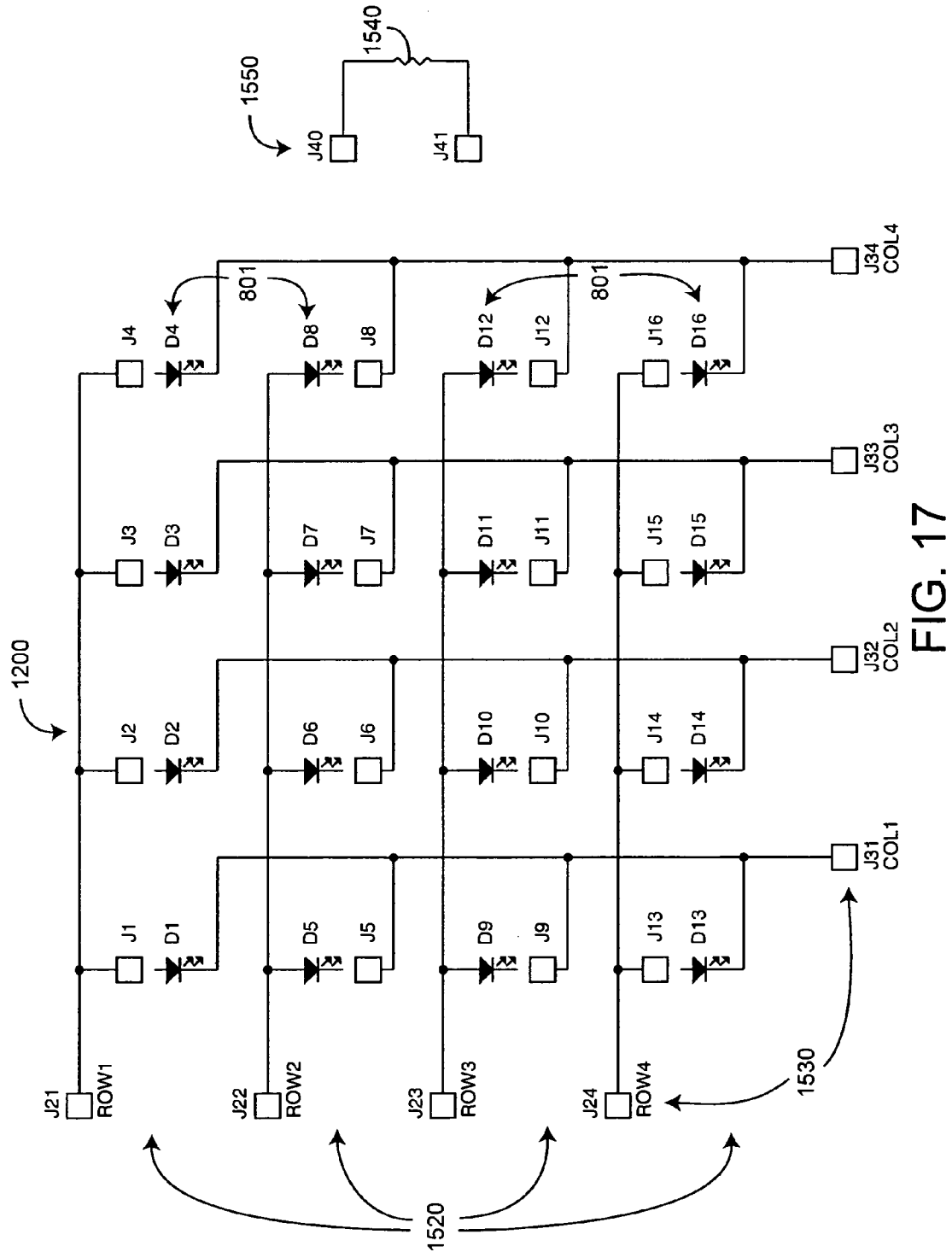


FIG. 16



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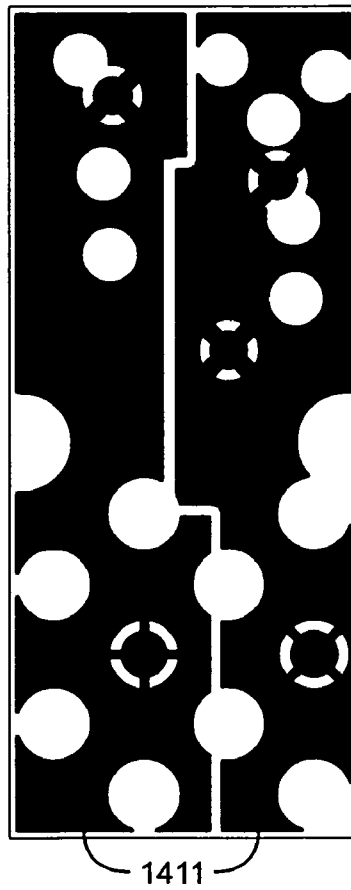
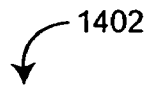


FIG. 18

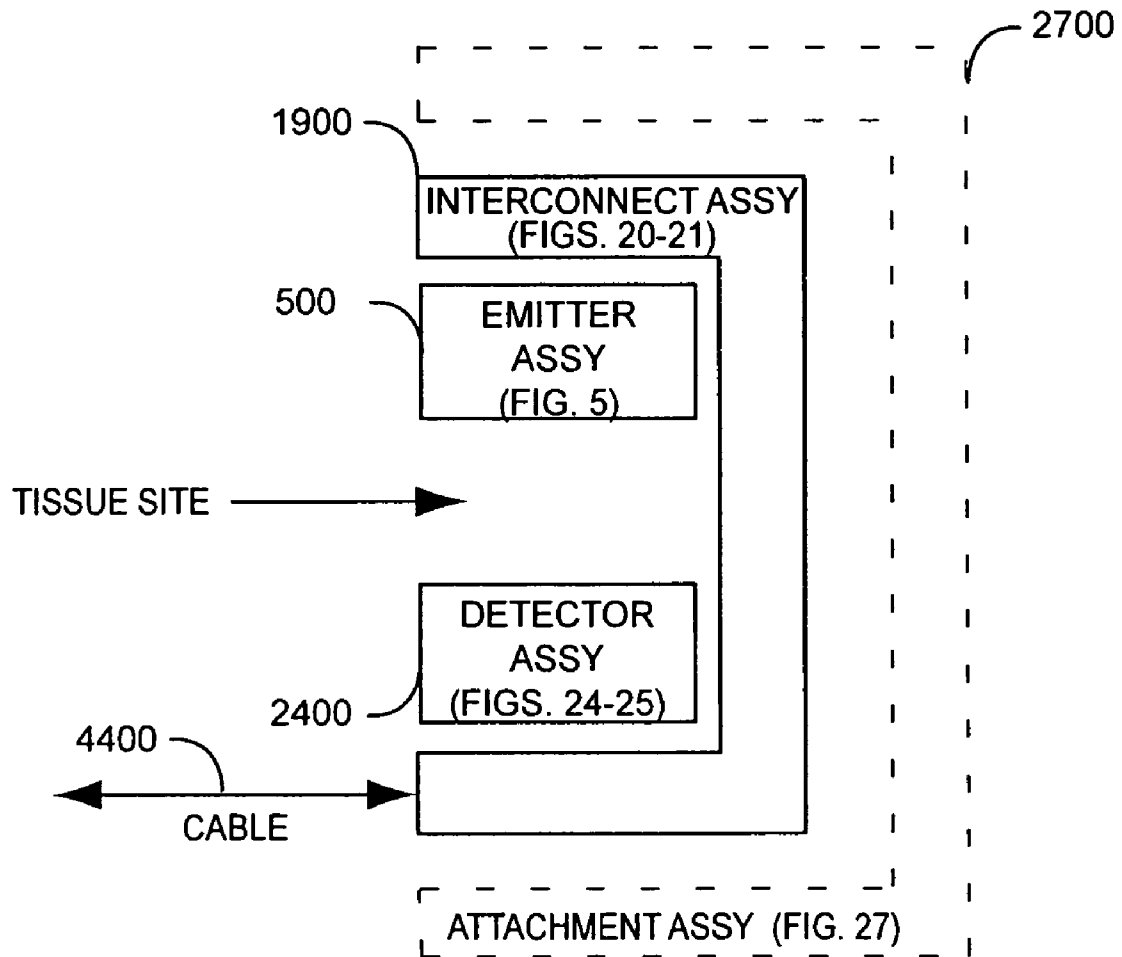


FIG. 19

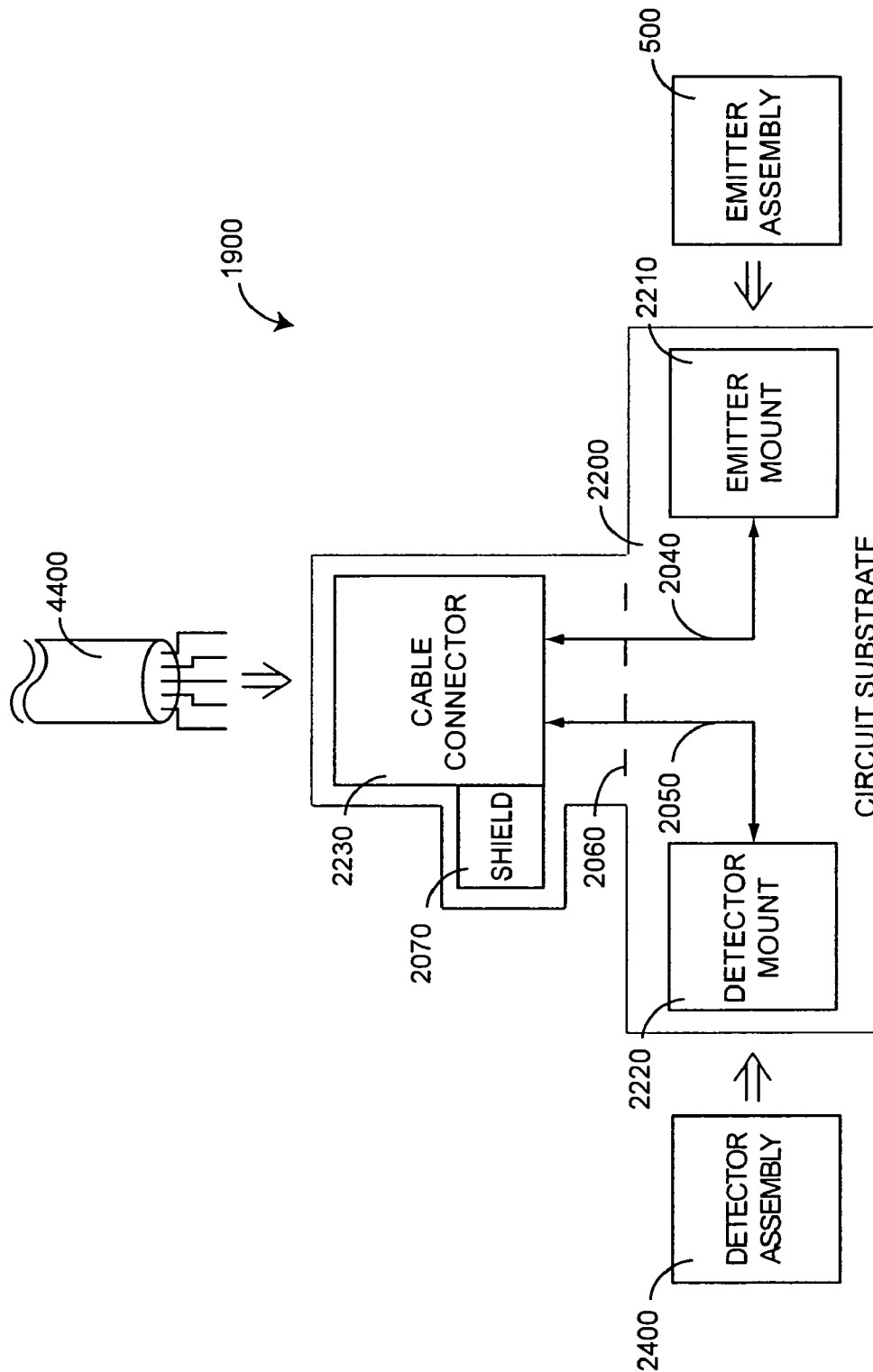


FIG. 20

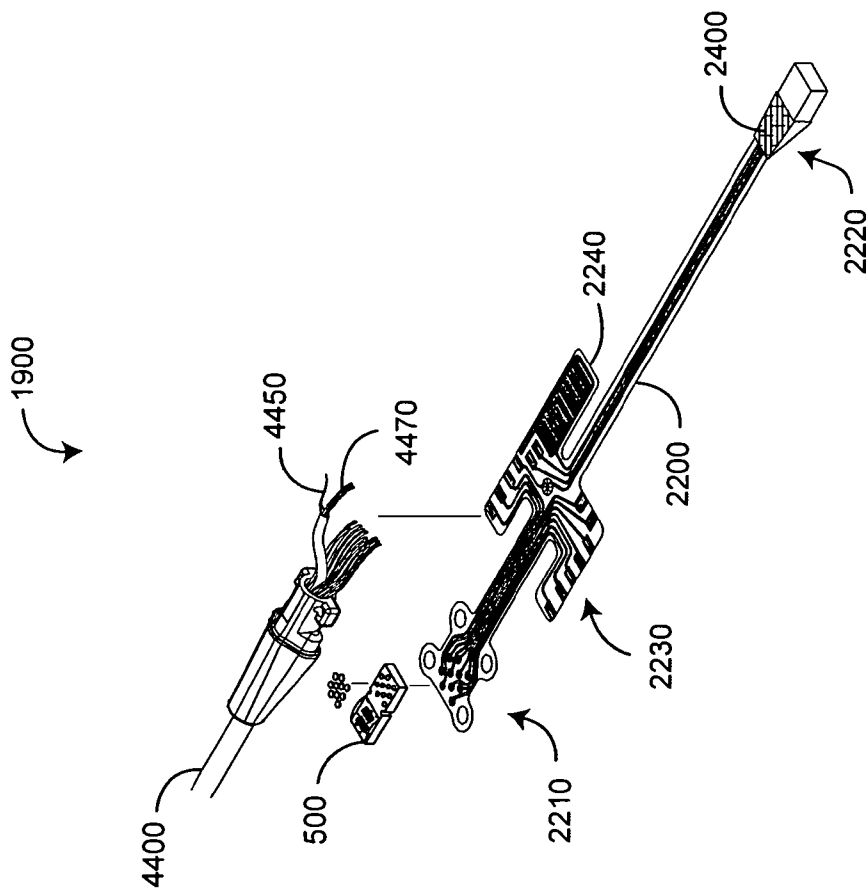


FIG. 21

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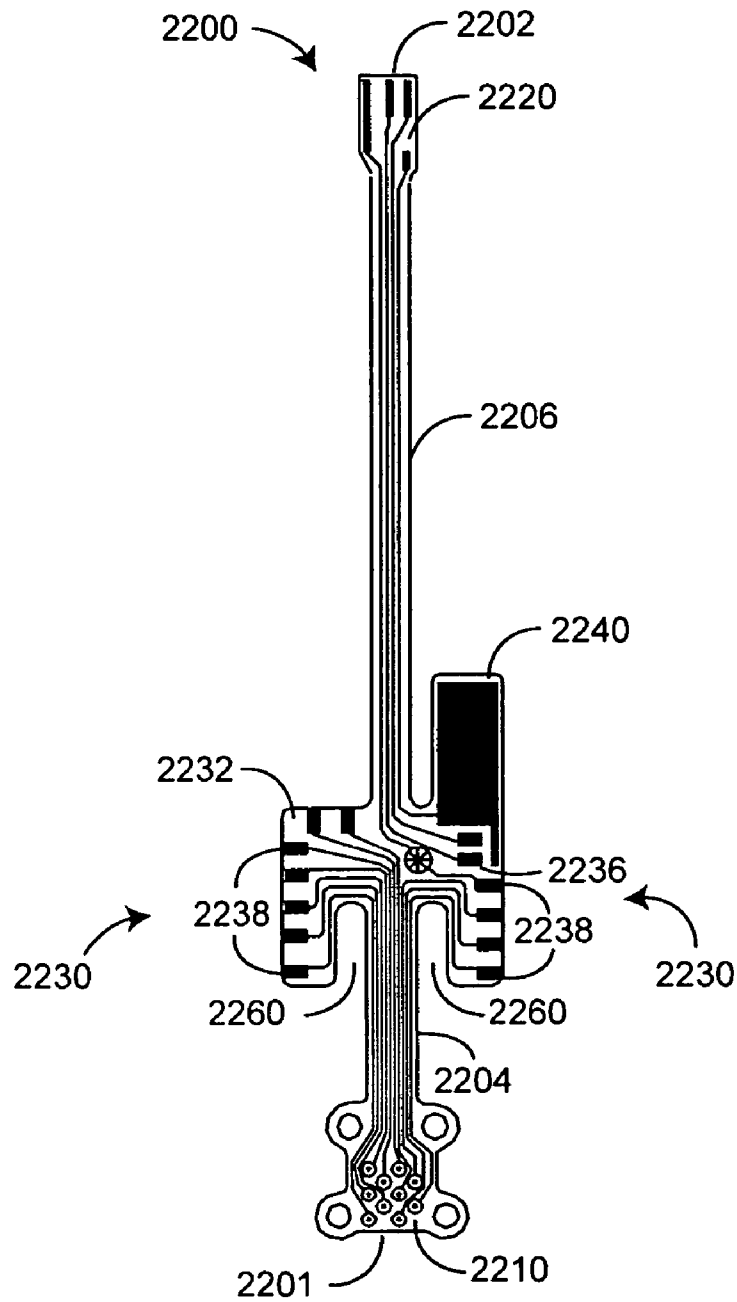


FIG. 22

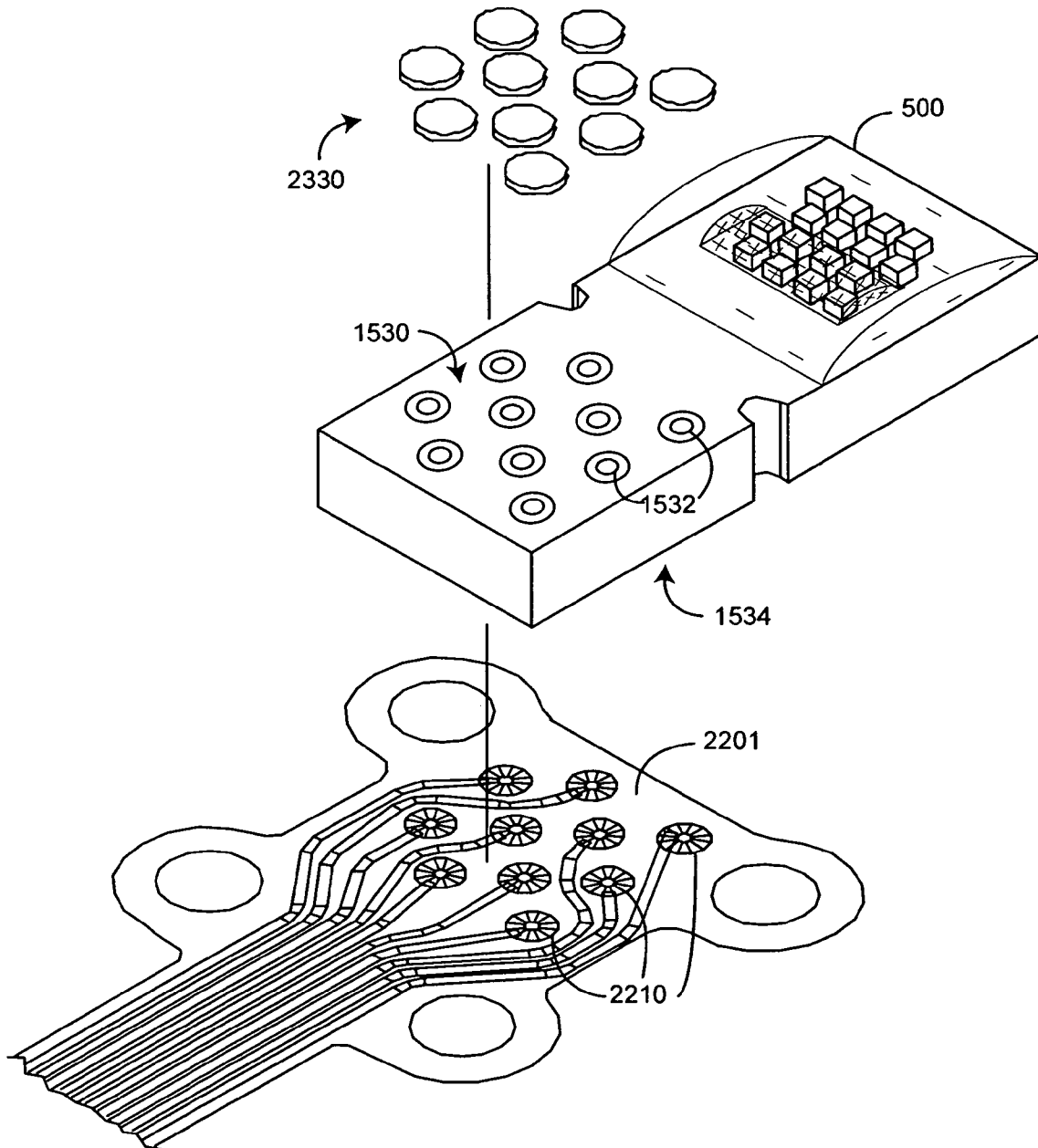


FIG. 23

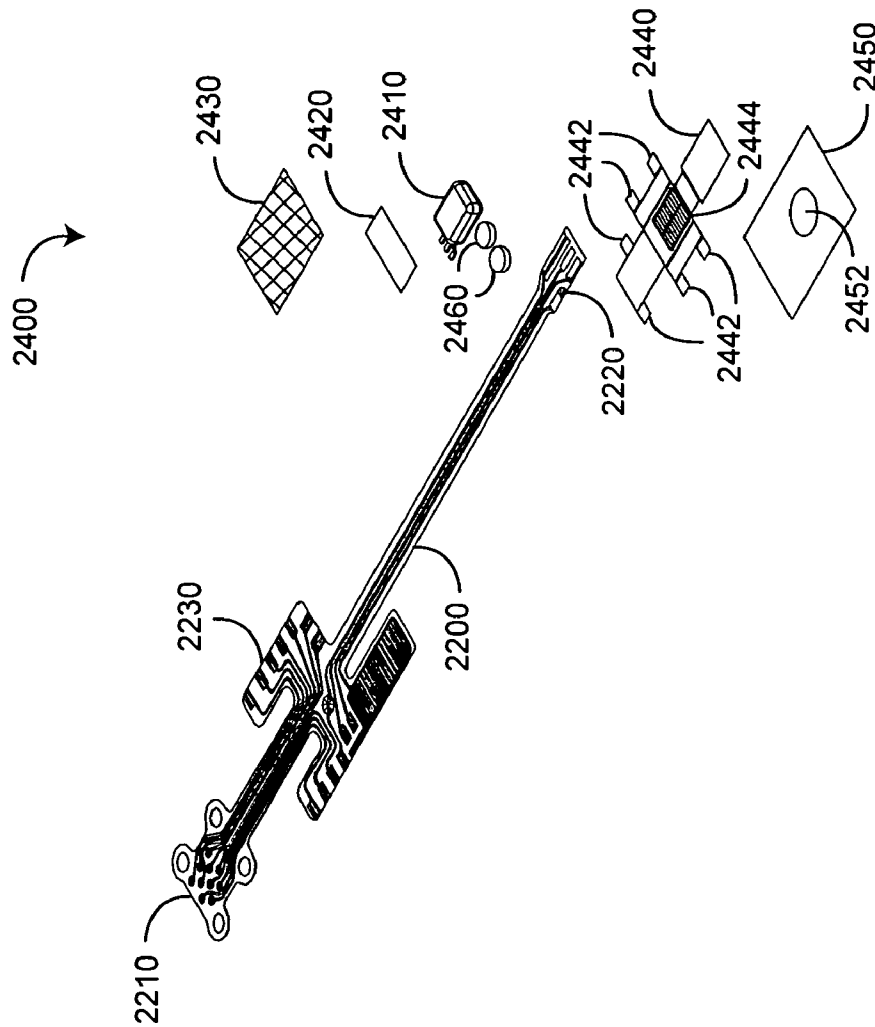


FIG. 24

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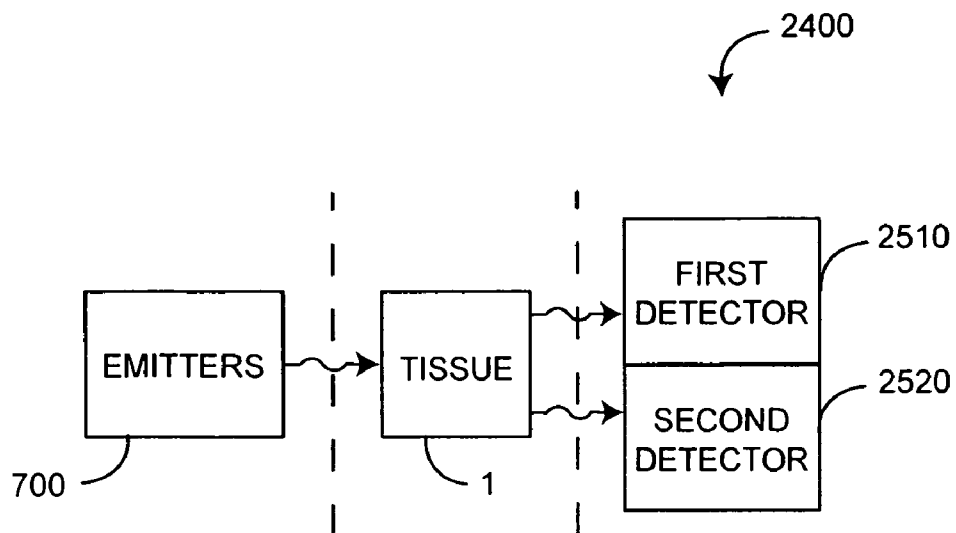


FIG. 25

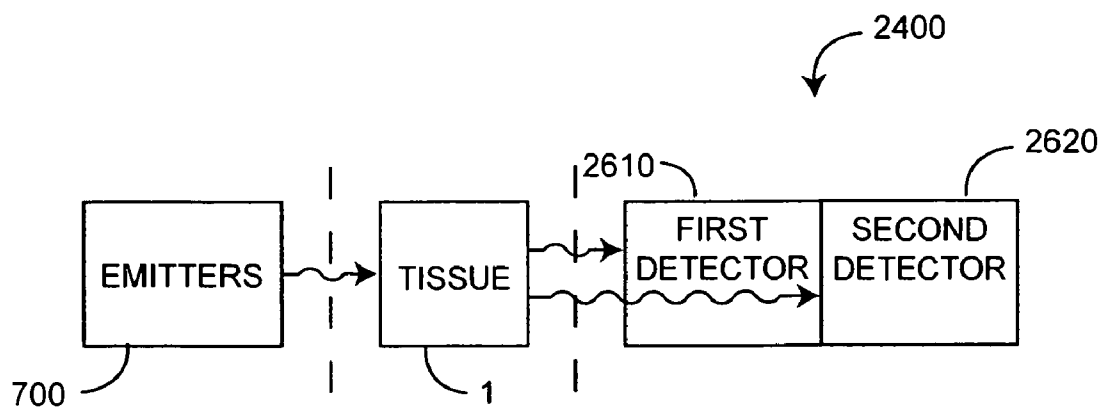


FIG. 26

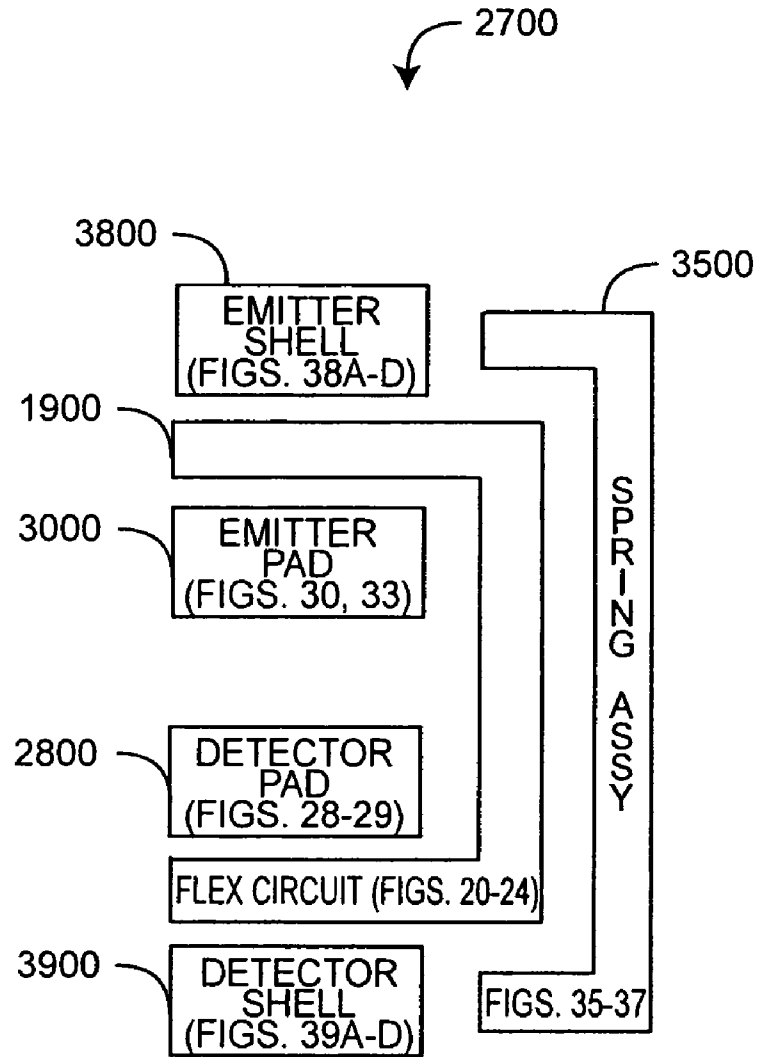


FIG. 27

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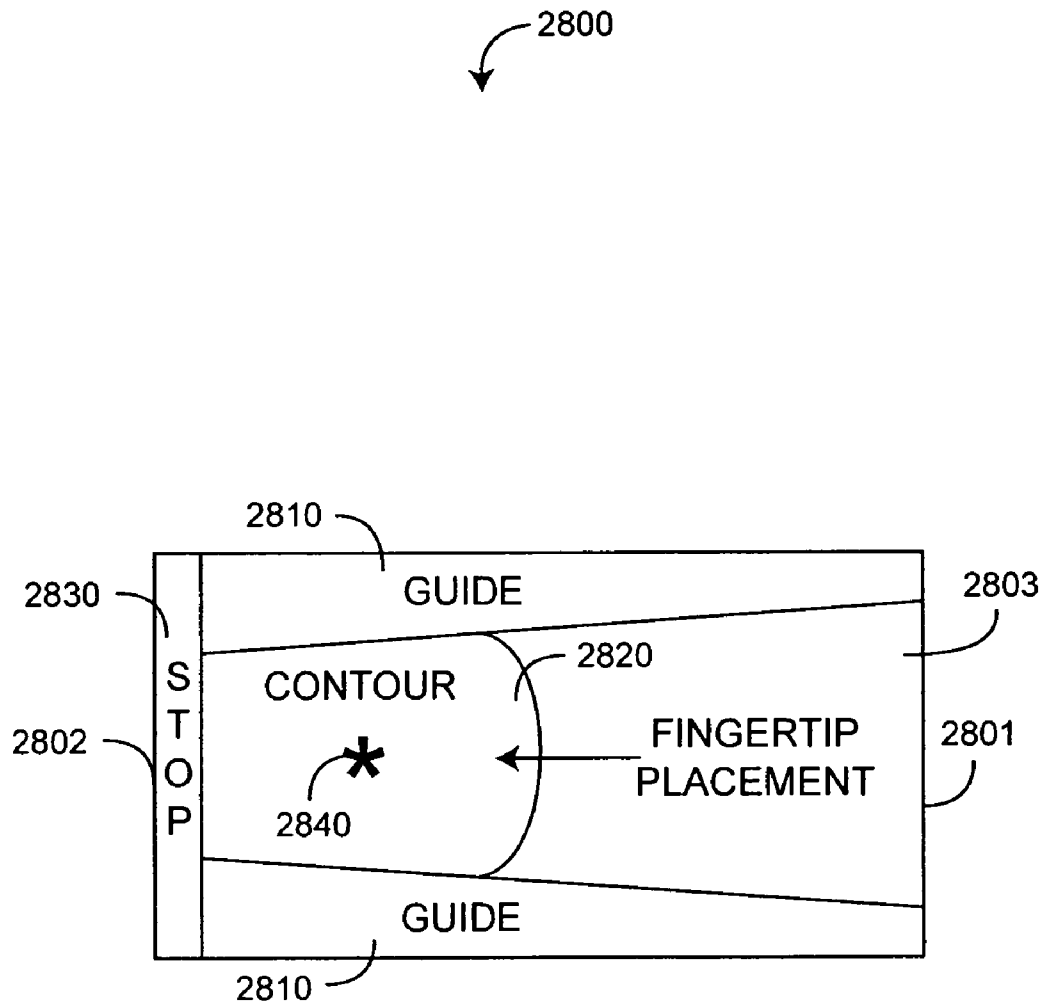


FIG. 28

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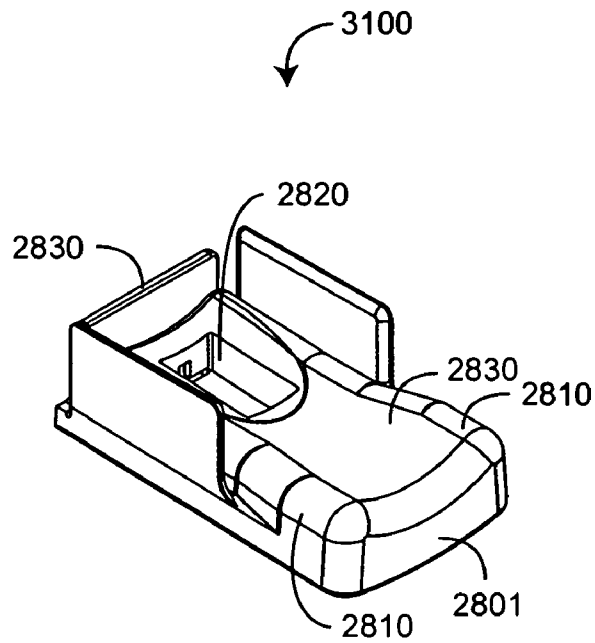


FIG. 29A

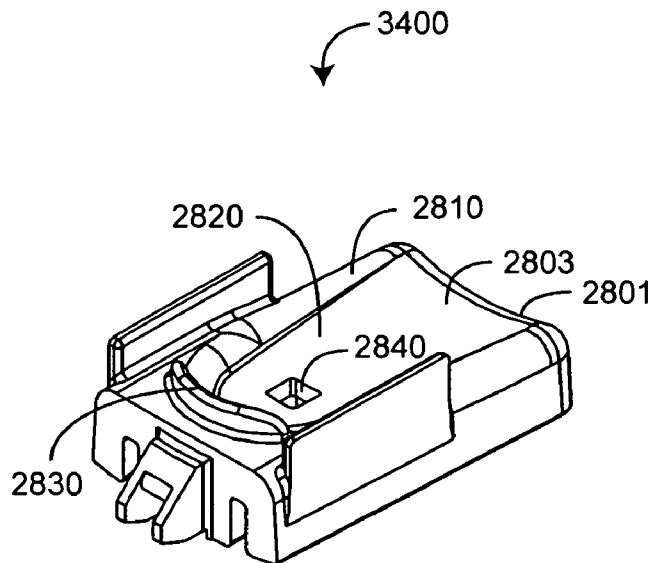


FIG. 29B

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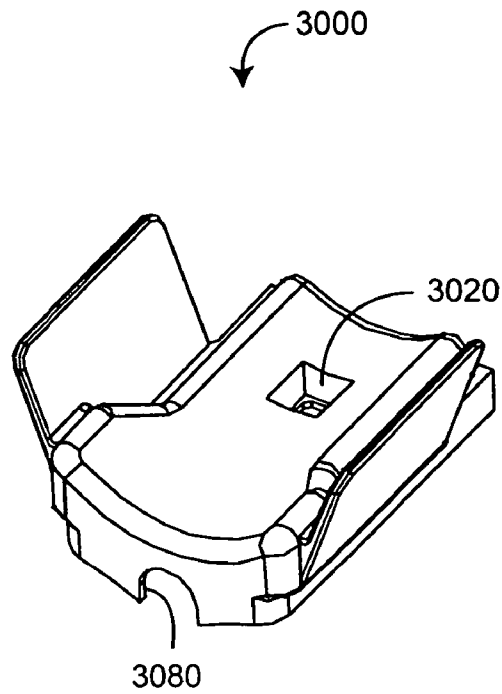


FIG. 30A

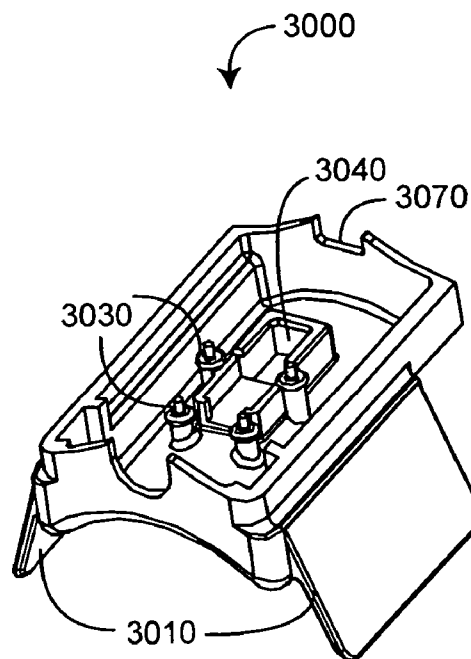


FIG. 30B

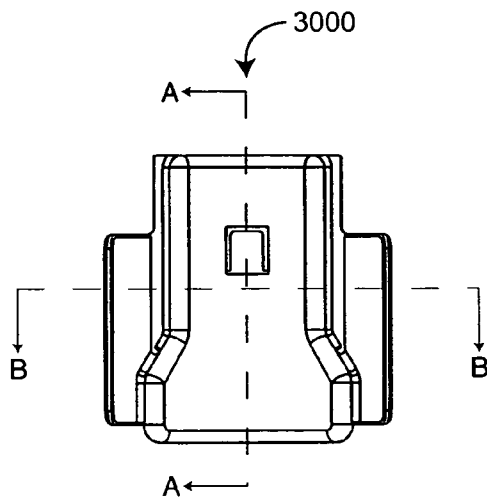


FIG. 30C

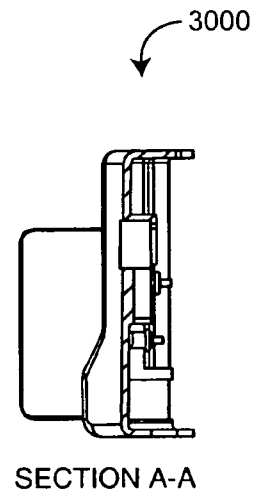


FIG. 30F

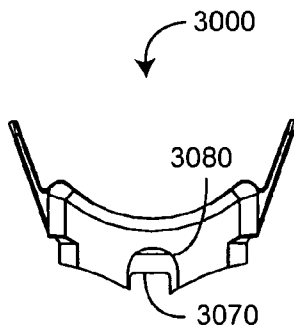


FIG. 30D

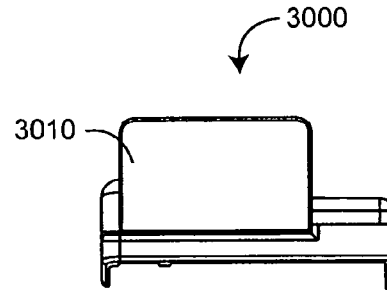


FIG. 30G

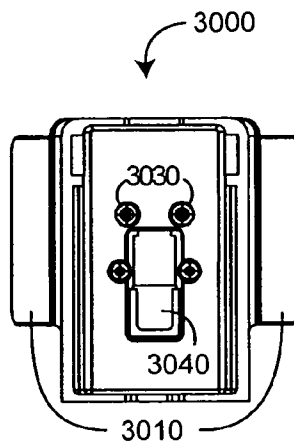


FIG. 30E

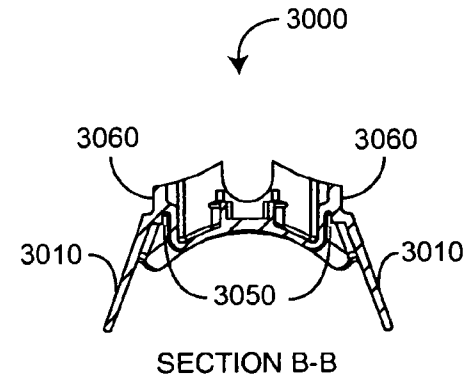


FIG. 30H

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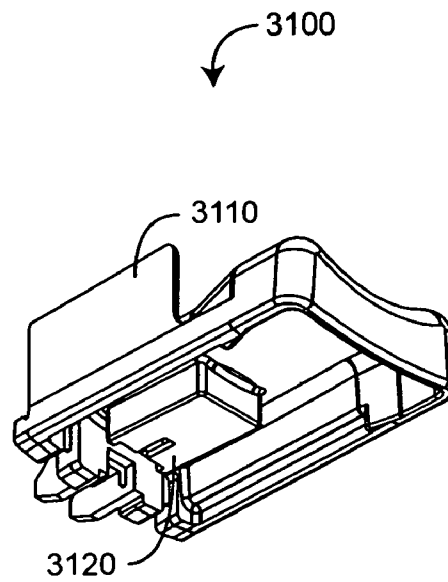


FIG. 31A

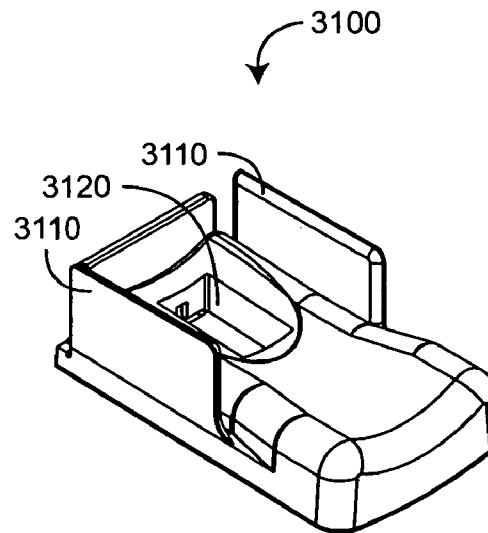


FIG. 31B

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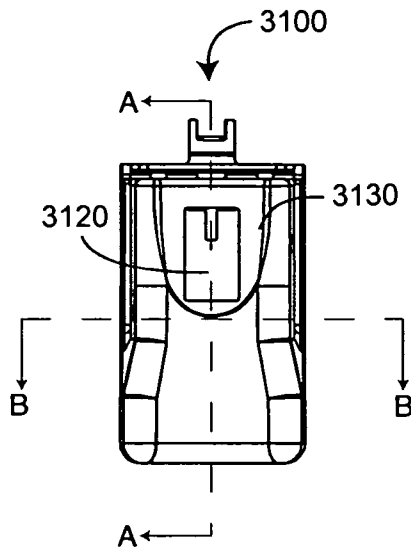
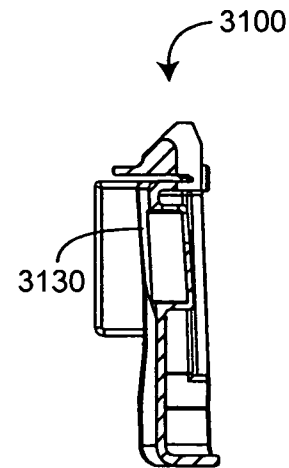


FIG. 31C



SECTION A-A

FIG. 31F

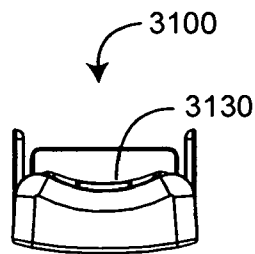


FIG. 31D

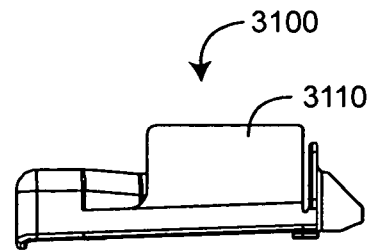


FIG. 31G

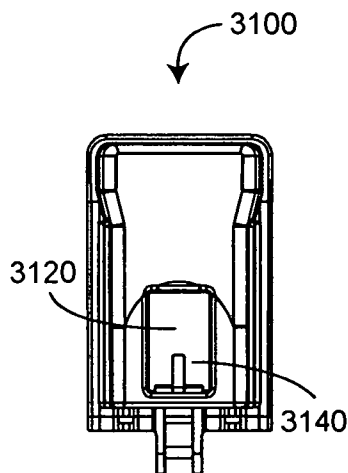
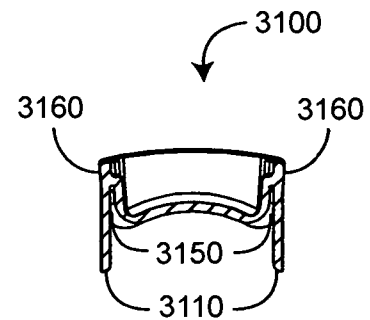


FIG. 31E



SECTION B-B

FIG. 31H

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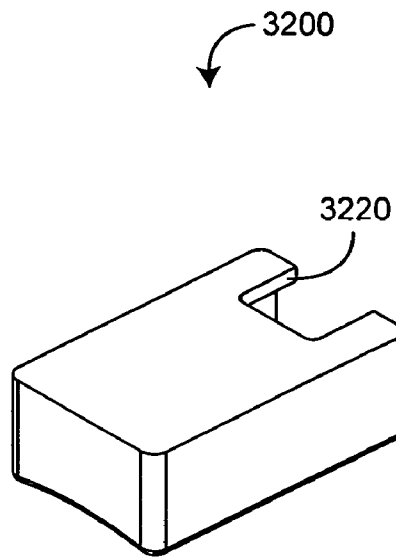


FIG. 32A

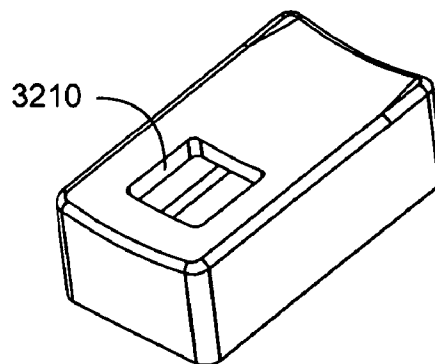


FIG. 32B

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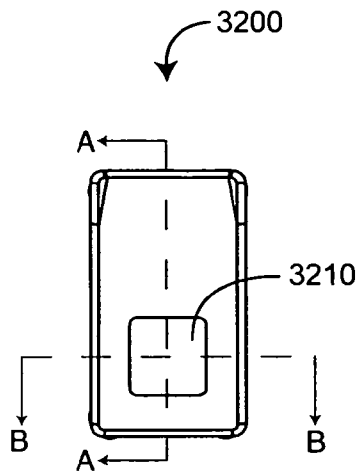
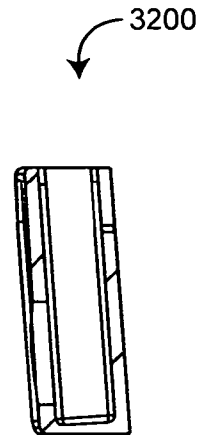


FIG. 32C



SECTION A-A

FIG. 32F

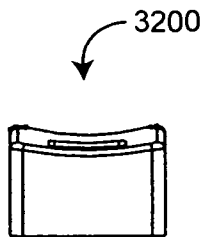


FIG. 32D

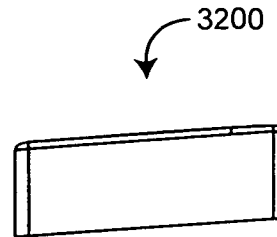


FIG. 32G

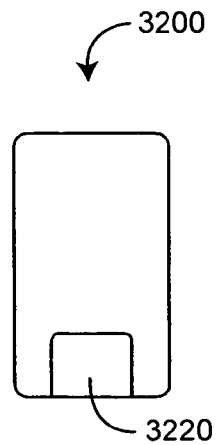
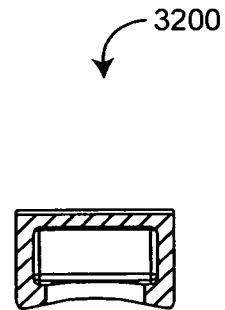


FIG. 32E



SECTION B-B

FIG. 32H

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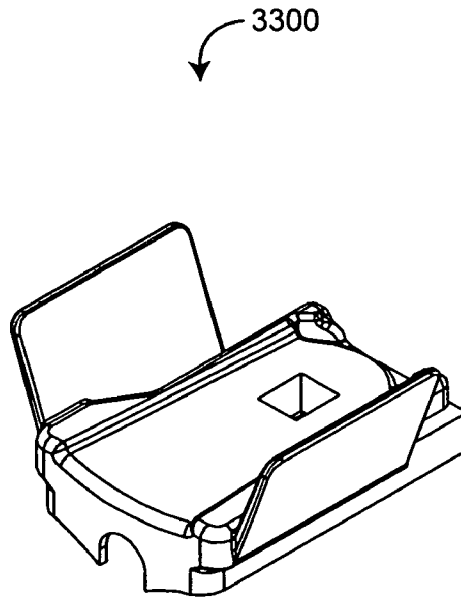


FIG. 33A

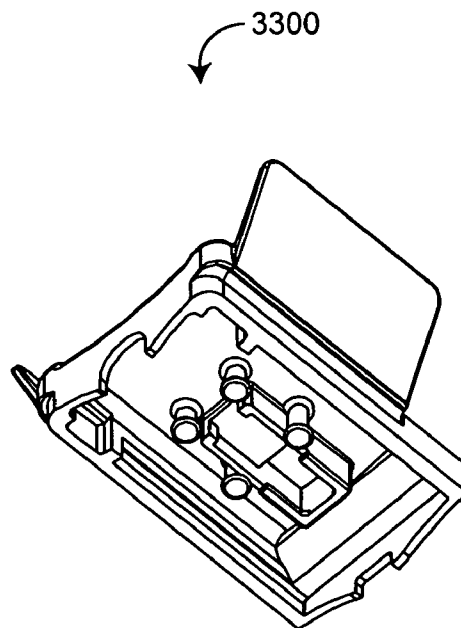


FIG. 33B

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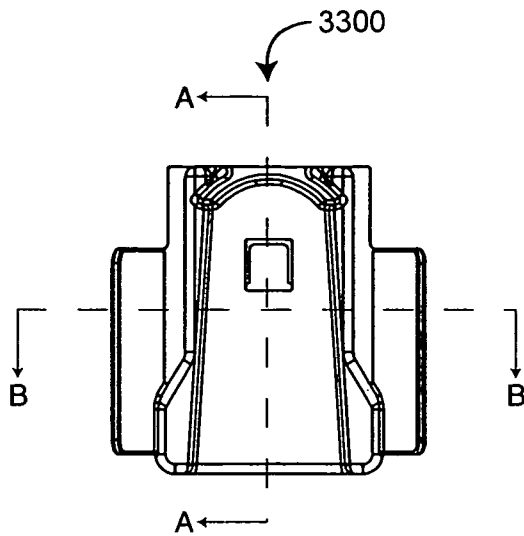


FIG. 33C

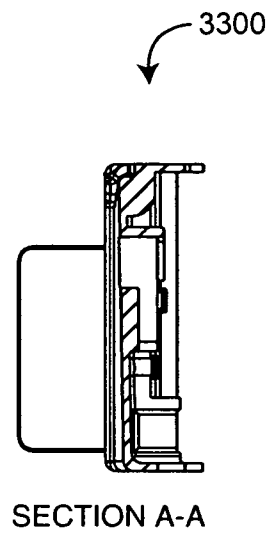


FIG. 33F

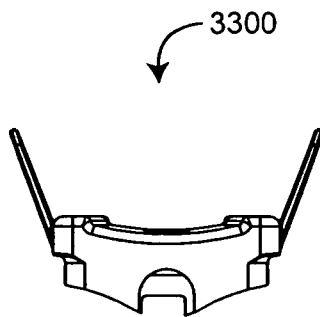


FIG. 33D

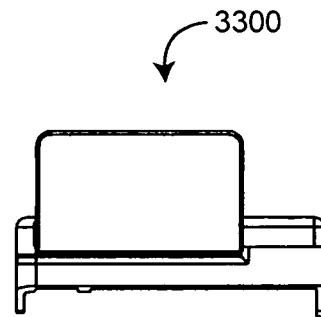


FIG. 33G

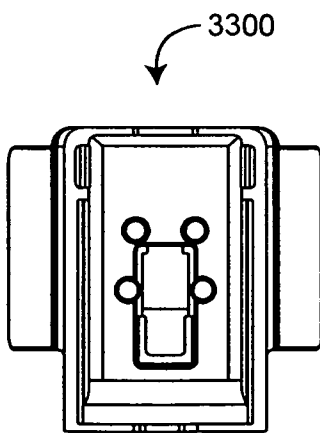


FIG. 33E

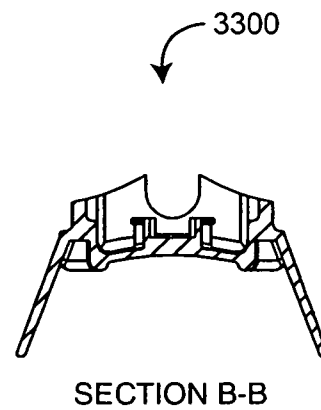


FIG. 33H

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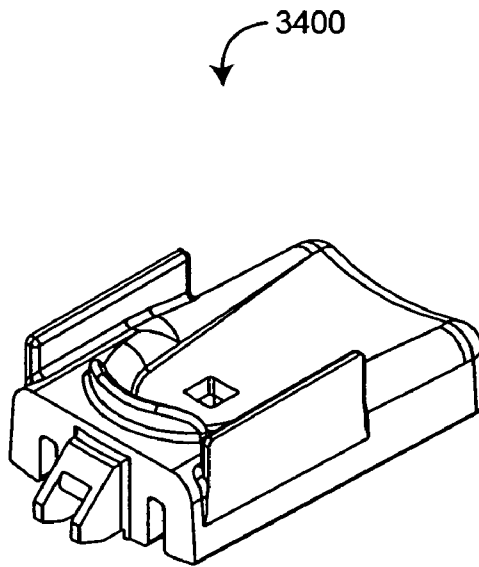


FIG. 34A

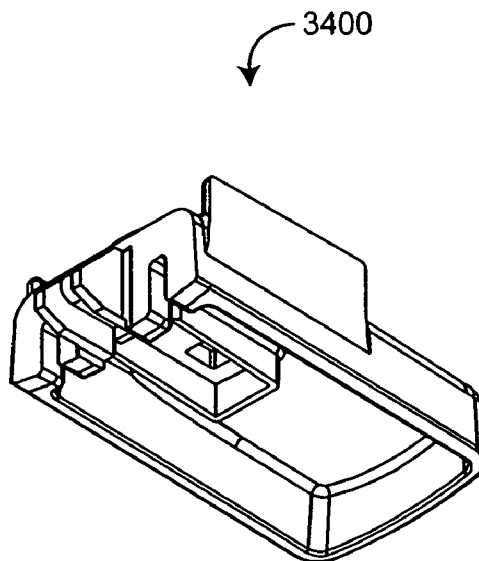


FIG. 34B

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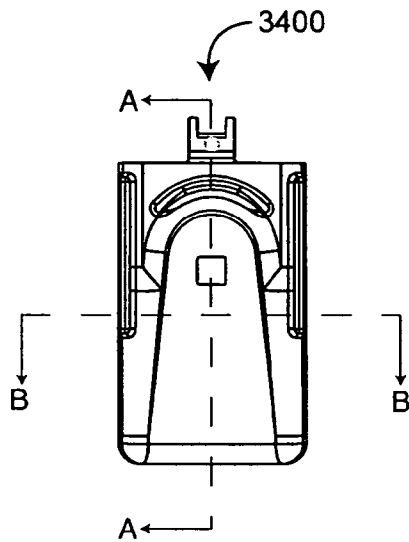
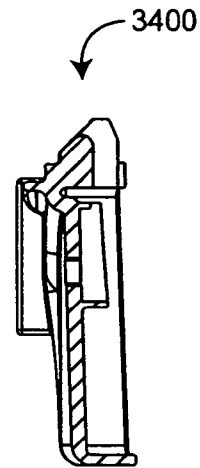


FIG. 34C



SECTION A-A

FIG. 34F

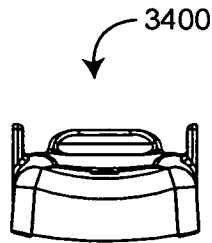


FIG. 34D

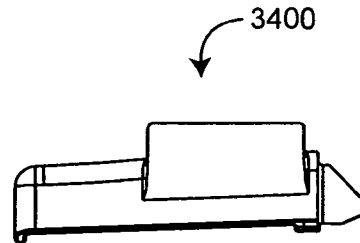


FIG. 34G

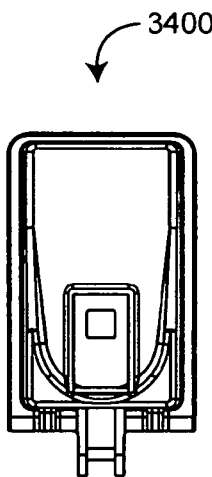
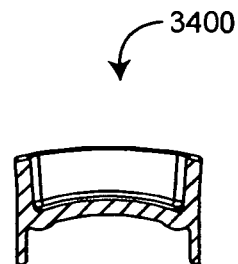


FIG. 34E



SECTION B-B

FIG. 34H

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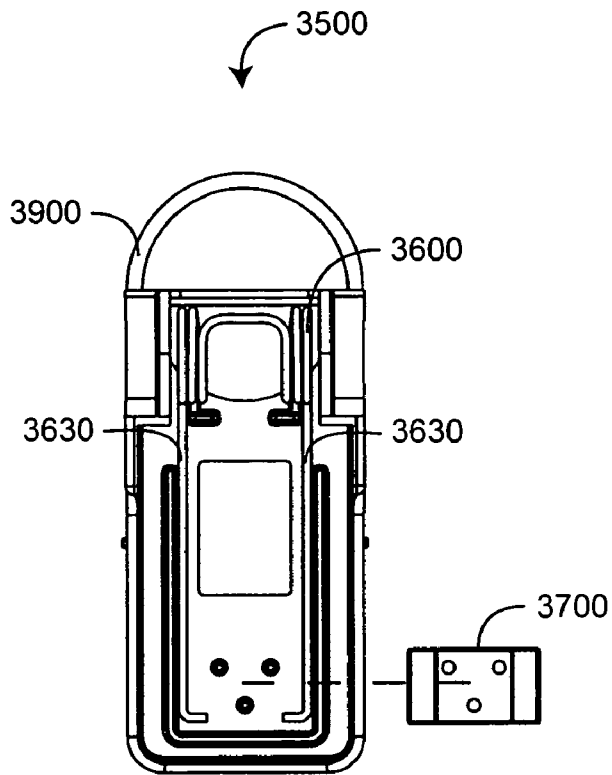


FIG. 35A

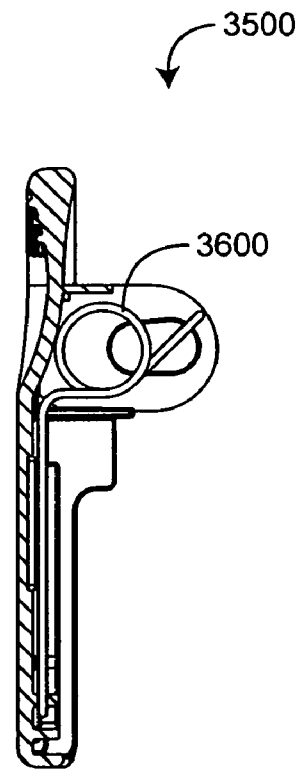


FIG. 35B

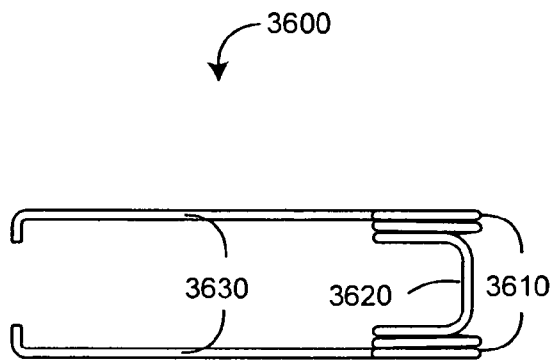


FIG. 36A

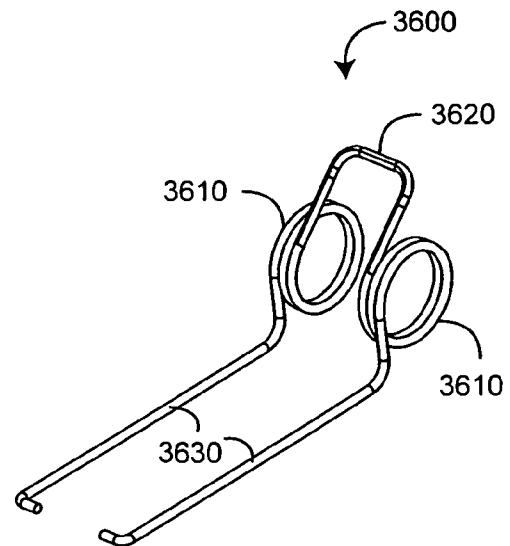


FIG. 36B

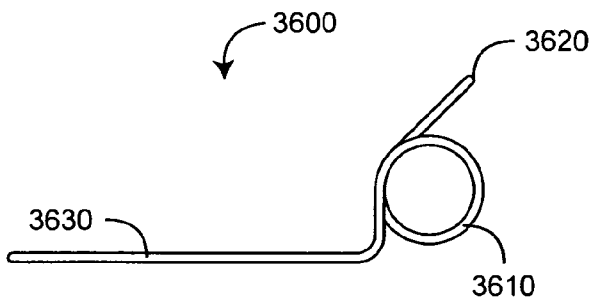


FIG. 36C

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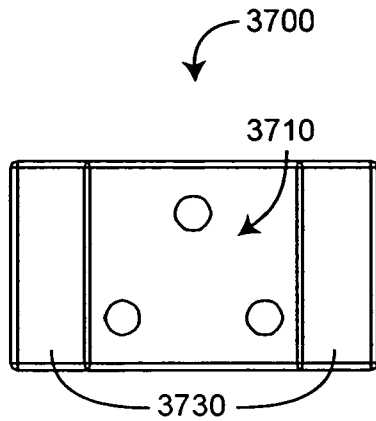


FIG. 37A

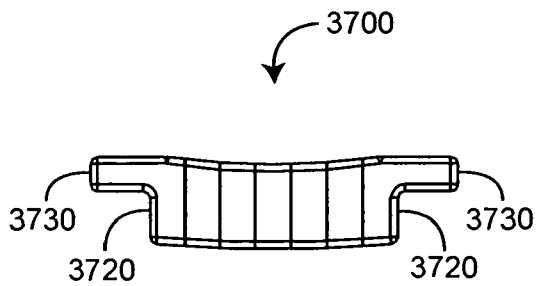


FIG. 37B

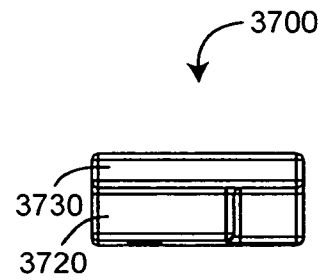


FIG. 37D

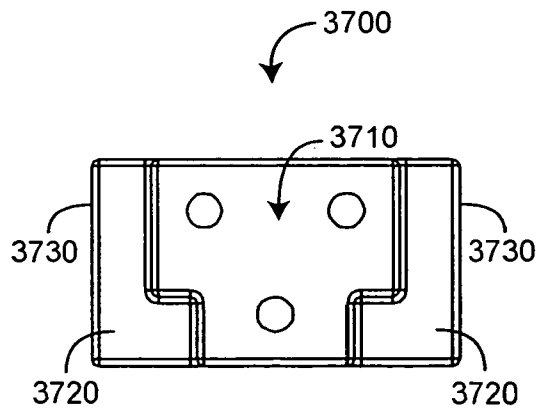


FIG. 37C

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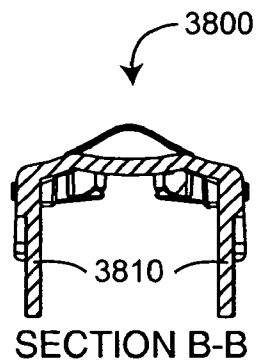


FIG. 38A

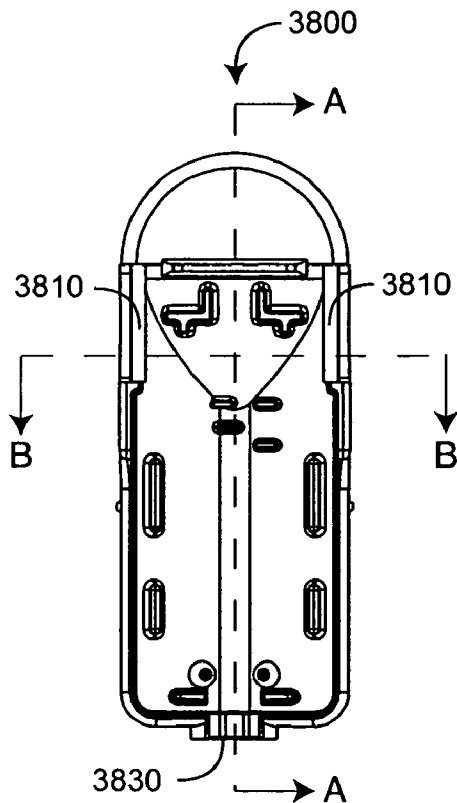
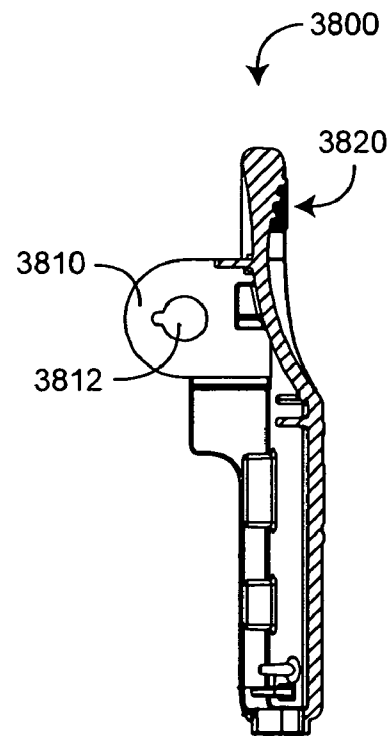


FIG. 38B



SECTION A-A
FIG. 38D

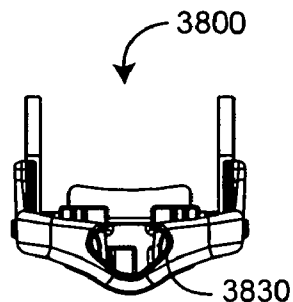


FIG. 38C

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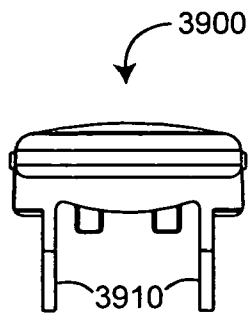


FIG. 39A

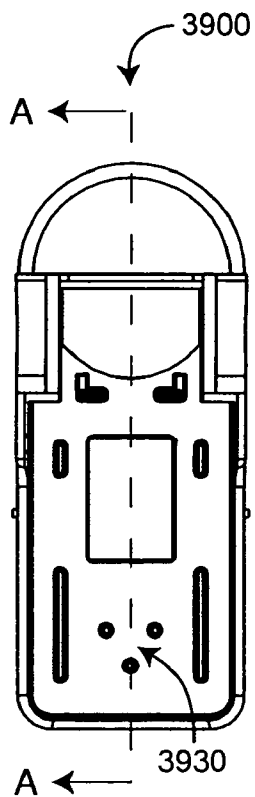


FIG. 39B

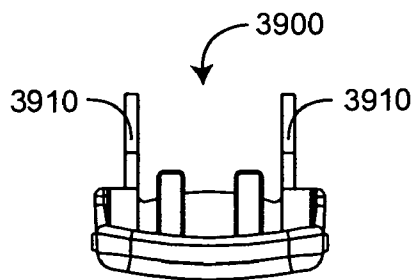
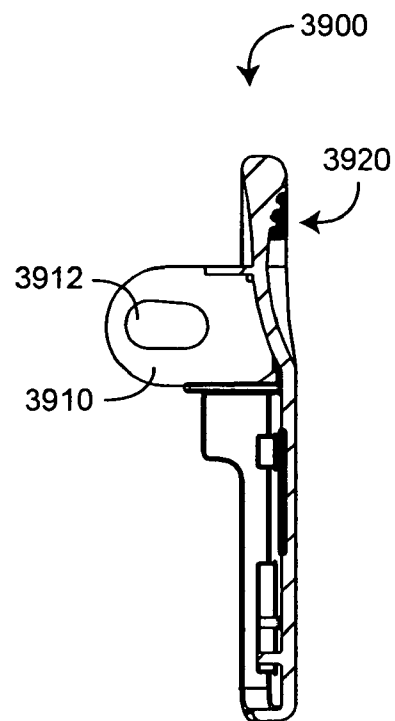


FIG. 39C



SECTION A-A
FIG. 39D

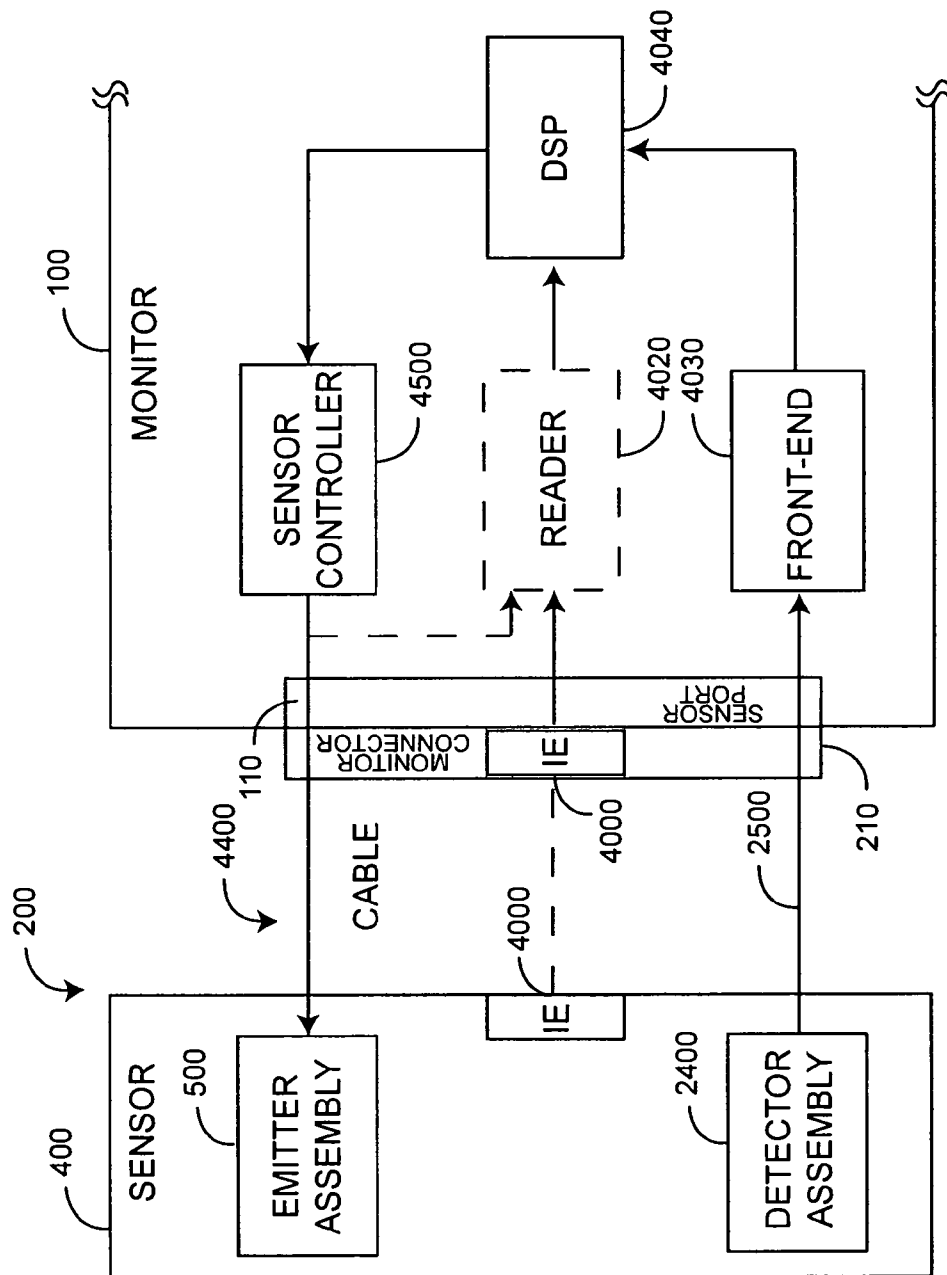


FIG. 40

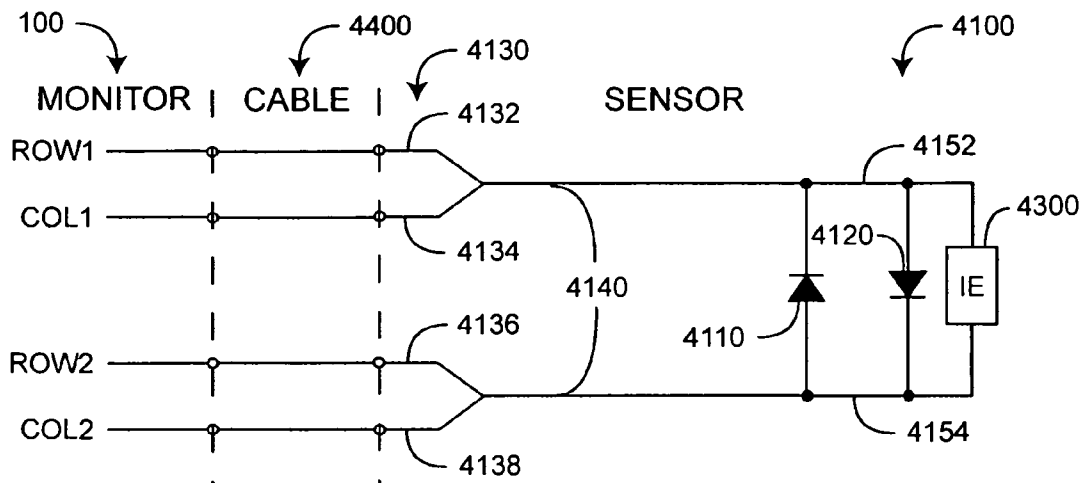


FIG. 41A

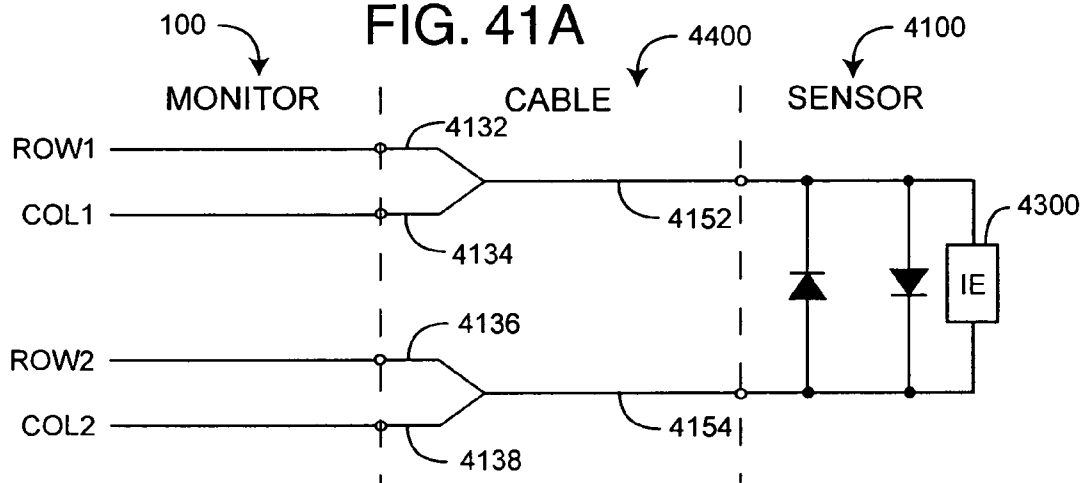


FIG. 41B

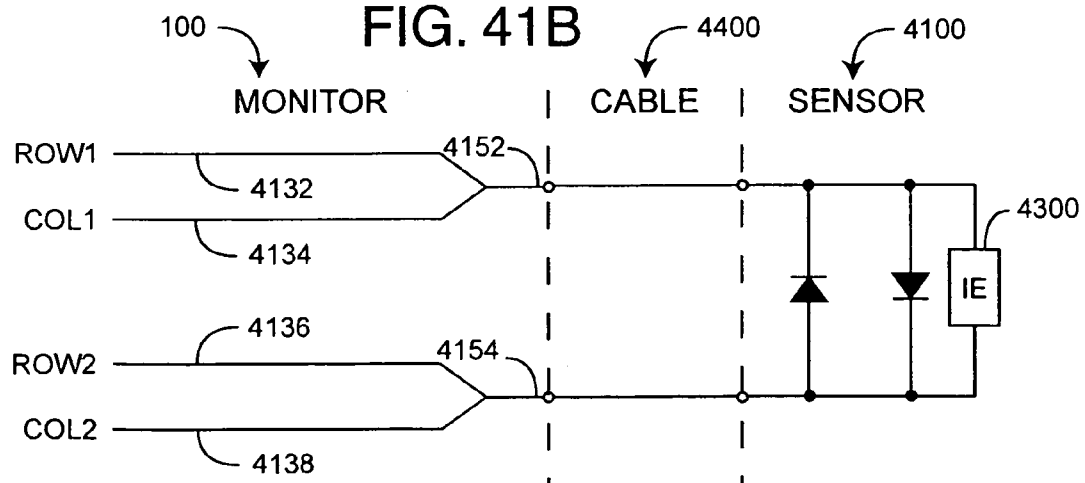


FIG. 41C

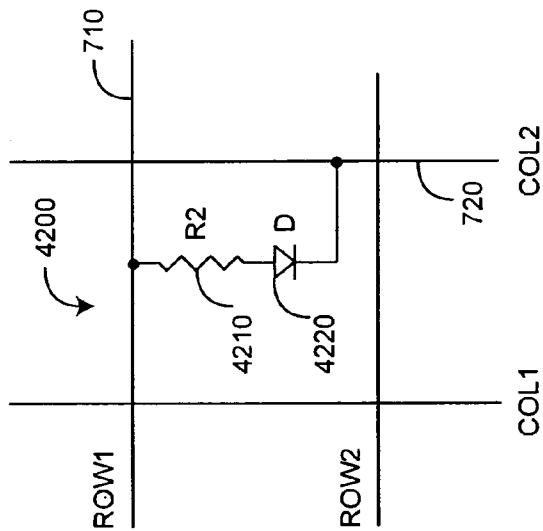


FIG. 42

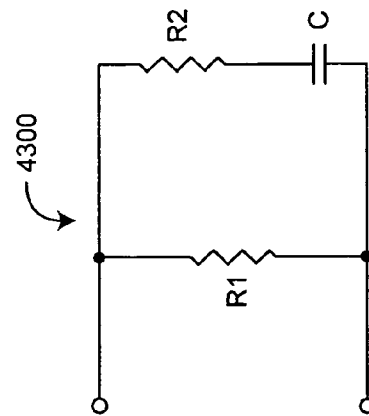


FIG. 43A

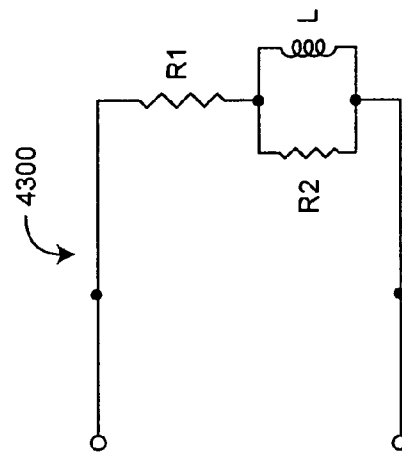


FIG. 43B

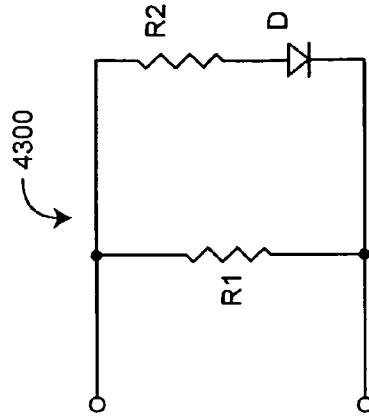


FIG. 43C

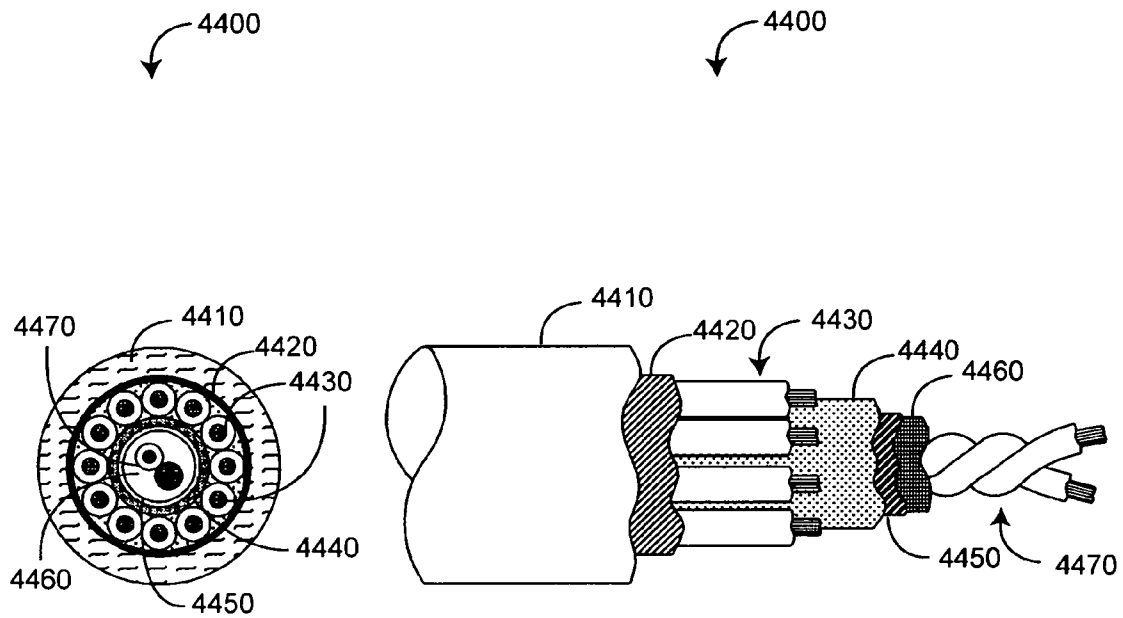


FIG. 44A

FIG. 44B

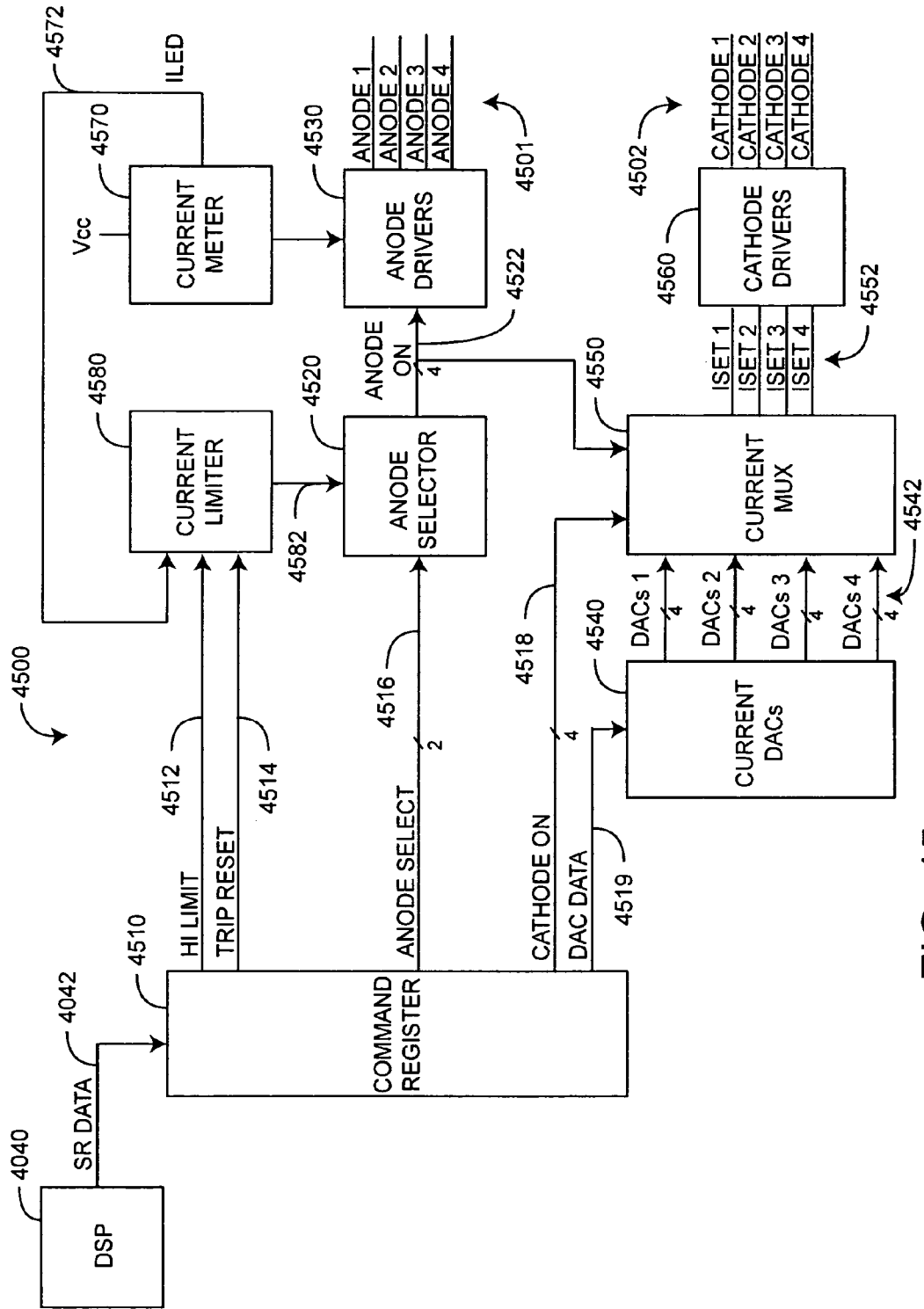


FIG. 45

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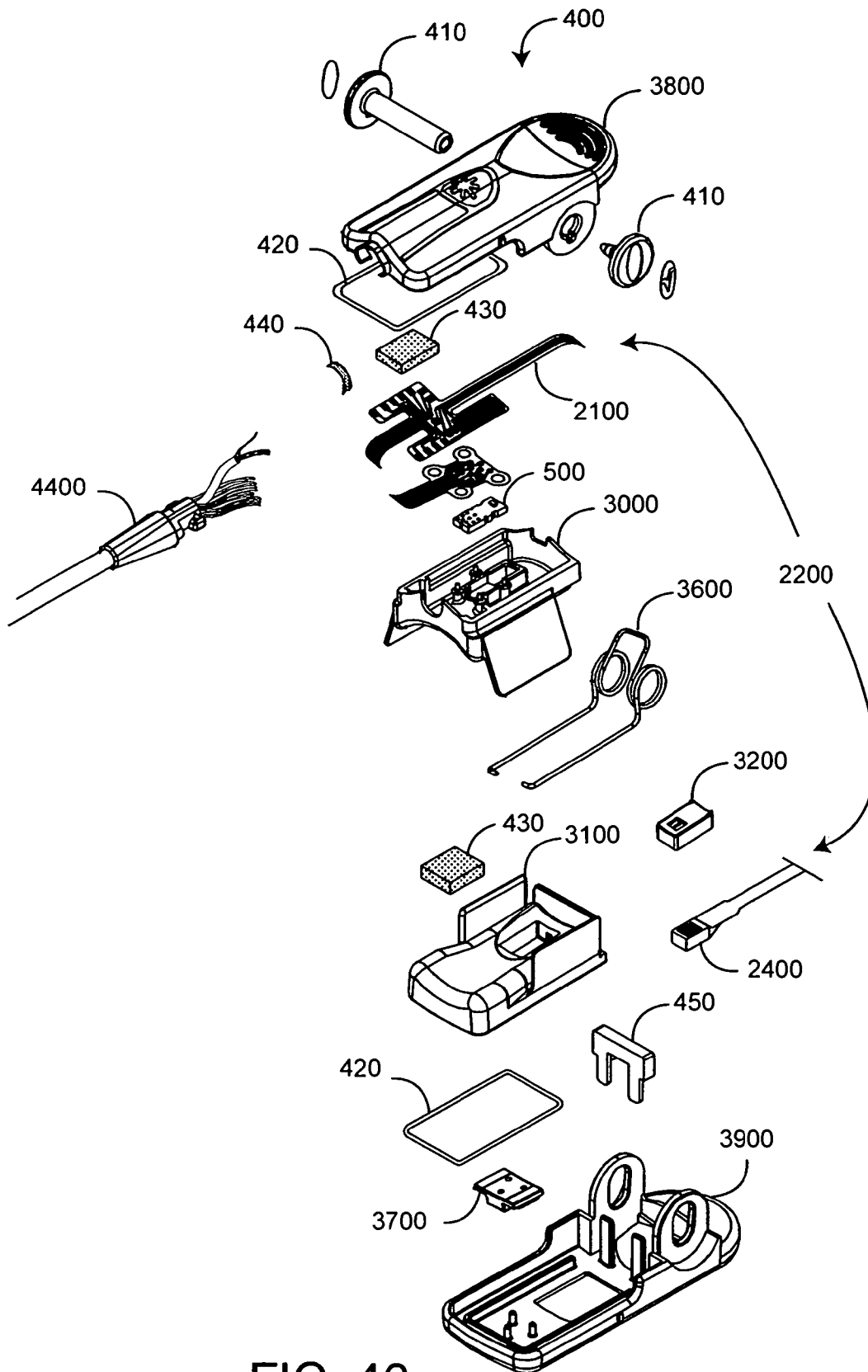


FIG. 46

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**MULTIPLE WAVELENGTH SENSOR
EMITTERS****PRIORITY CLAIM TO RELATED PROVISIONAL
APPLICATIONS**

The present application claims priority benefit under 35 U.S.C. §119(e) to U.S. Provisional Patent Application Ser. No. 60/657,596, filed Mar. 1, 2005, entitled "Multiple Wavelength Sensor," No. 60/657,281, filed Mar. 1, 2005, entitled "Physiological Parameter Confidence Measure," No. 60/657,268, filed Mar. 1, 2005, entitled "Configurable Physiological Measurement System," and No. 60/657,759, filed Mar. 1, 2005, entitled "Noninvasive Multi-Parameter Patient Monitor." The present application incorporates the foregoing disclosures herein by reference.

**INCORPORATION BY REFERENCE OF
COPENDING RELATED APPLICATIONS**

The present application is related to the following copping U.S. utility applications:

	App. Sr. No.	Filing Date	Title	Atty Dock.
1	11/366,995	Mar. 1, 2006	Multiple Wavelength Sensor Equalization	MLR.003A
2	11/366,209	Mar. 1, 2006	Multiple Wavelength Sensor Substrate	MLR.004A
3	11/366,210	Mar. 1, 2006	Multiple Wavelength Sensor Interconnect	MLR.005A
4	11/366,833	Mar. 1, 2006	Multiple Wavelength Sensor Attachment	MLR.006A
5	11/366,997	Mar. 1, 2006	Multiple Wavelength Sensor Drivers	MLR.009A
6	11/367,034	Mar. 1, 2006	Physiological Parameter Confidence Measure	MLR.010A
7	11/367,036	Mar. 1, 2006	Configurable Physiological Measurement System	MLR.011A
8	11/367,033	Mar. 1, 2006	Noninvasive Multi-Parameter Patient Monitor	MLR.012A
9	11/367,014	Mar. 1, 2006	Noninvasive Multi-Parameter Patient Monitor	MLR.013A
10	11/366,208	Mar. 1, 2006	Noninvasive Multi-Parameter Patient Monitor	MLR.014A

The present application incorporates the foregoing disclosures herein by reference.

BACKGROUND OF THE INVENTION

Spectroscopy is a common technique for measuring the concentration of organic and some inorganic constituents of a solution. The theoretical basis of this technique is the Beer-Lambert law, which states that the concentration c_i of an absorbent in solution can be determined by the intensity of light transmitted through the solution, knowing the path-length d_λ , the intensity of the incident light $I_{0,\lambda}$, and the extinction coefficient $\epsilon_{i,\lambda}$ at a particular wavelength λ . In generalized form, the Beer-Lambert law is expressed as:

$$I_\lambda = I_{0,\lambda} e^{-d_\lambda \mu_{a,\lambda}} \quad (1)$$

$$\mu_{a,\lambda} = \sum_{i=1}^n \epsilon_{i,\lambda} \cdot c_i \quad (2)$$

where $\mu_{a,\lambda}$ is the bulk absorption coefficient and represents the probability of absorption per unit length. The minimum

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number of discrete wavelengths that are required to solve EQS. 1-2 are the number of significant absorbers that are present in the solution.

A practical application of this technique is pulse oximetry, which utilizes a noninvasive sensor to measure oxygen saturation (SpO_2) and pulse rate. In general, the sensor has light emitting diodes (LEDs) that transmit optical radiation of red and infrared wavelengths into a tissue site and a detector that responds to the intensity of the optical radiation after absorption (e.g., by transmission or transreflectance) by pulsatile arterial blood flowing within the tissue site. Based on this response, a processor determines measurements for SpO_2 , pulse rate, and can output representative plethysmographic waveforms. Thus, "pulse oximetry" as used herein encompasses its broad ordinary meaning known to one of skill in the art, which includes at least those noninvasive procedures for measuring parameters of circulating blood through spectroscopy. Moreover, "plethysmograph" as used herein (commonly referred to as "photoplethysmograph"), encompasses its broad ordinary meaning known to one of skill in the art, which includes at least data representative of a change in the absorption of particular wavelengths of light as a function of the changes in body tissue resulting from pulsing blood. Pulse oximeters capable of reading through motion induced noise are available from Masimo Corporation ("Masimo") of Irvine, Calif. Moreover, portable and other oximeters capable of reading through motion induced noise are disclosed in at least U.S. Pat. Nos. 6,770,028, 6,658,276, 6,157,850, 6,002,952, 5,769,785, and 5,758,644, which are owned by Masimo and are incorporated by reference herein. Such reading through motion oximeters have gained rapid acceptance in a wide variety of medical applications, including surgical wards, intensive care and neonatal units, general wards, home care, physical training, and virtually all types of monitoring scenarios.

SUMMARY OF THE INVENTION

There is a need to noninvasively measure multiple physiological parameters, other than, or in addition to, oxygen saturation and pulse rate. For example, hemoglobin species that are also significant under certain circumstances are carboxyhemoglobin and methemoglobin. Other blood parameters that may be measured to provide important clinical information are fractional oxygen saturation, total hemoglobin (Hbt), bilirubin and blood glucose, to name a few.

One aspect of a physiological sensor is light emitting sources, each activated by addressing at least one row and at least one column of an electrical grid. The light emitting sources transmit light having multiple wavelengths and a detector is responsive to the transmitted light after attenuation by body tissue.

Another aspect of a physiological sensor is light emitting sources capable of transmitting light having multiple wavelengths. Each of the light emitting sources includes a first contact and a second contact. The first contacts of a first set of the light emitting sources are in communication with a first conductor and the second contacts of a second set of the light emitting sources are in communication with a second conductor. A detector is capable of detecting the transmitted light attenuated by body tissue and outputting a signal indicative of at least one physiological parameter of the body tissue. At least one light emitting source of the first set and at least one light emitting source of the second set are not common to the first and second sets. Further, each of the first set and the second set comprises at least two of the light emitting sources.

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A further aspect of a physiological sensor sequentially addresses light emitting sources using conductors of an electrical grid so as to emit light having multiple wavelengths that when attenuated by body tissue is indicative of at least one physiological characteristic. The emitted light is detected after attenuation by body tissue.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of a physiological measurement system utilizing a multiple wavelength sensor;

FIGS. 2A-C are perspective views of multiple wavelength sensor embodiments;

FIG. 3 is a general block diagram of a multiple wavelength sensor and sensor controller;

FIG. 4 is an exploded perspective view of a multiple wavelength sensor embodiment;

FIG. 5 is a general block diagram of an emitter assembly;

FIG. 6 is a perspective view of an emitter assembly embodiment;

FIG. 7 is a general block diagram of an emitter array;

FIG. 8 is a schematic diagram of an emitter array embodiment;

FIG. 9 is a general block diagram of equalization;

FIGS. 10A-D are block diagrams of various equalization embodiments;

FIGS. 11A-C are perspective views of an emitter assembly incorporating various equalization embodiments;

FIG. 12 is a general block diagram of an emitter substrate;

FIGS. 13-14 are top and detailed side views of an emitter substrate embodiment;

FIG. 15-16 are top and bottom component layout views of an emitter substrate embodiment;

FIG. 17 is a schematic diagram of an emitter substrate embodiment;

FIG. 18 is a plan view of an inner layer of an emitter substrate embodiment;

FIG. 19 is a general block diagram of an interconnect assembly in relationship to other sensor assemblies;

FIG. 20 is a block diagram of an interconnect assembly embodiment;

FIG. 21 is a partially-exploded perspective view of a flex circuit assembly embodiment of an interconnect assembly;

FIG. 22 is a top plan view of a flex circuit;

FIG. 23 is an exploded perspective view of an emitter portion of a flex circuit assembly;

FIG. 24 is an exploded perspective view of a detector assembly embodiment;

FIGS. 25-26 are block diagrams of adjacent detector and stacked detector embodiments;

FIG. 27 is a block diagram of a finger clip embodiment of an attachment assembly;

FIG. 28 is a general block diagram of a detector pad;

FIGS. 29A-B are perspective views of detector pad embodiments;

FIGS. 30A-H are perspective bottom, perspective top, bottom, back, top, side cross sectional, side, and front cross sectional views of an emitter pad embodiment;

FIGS. 31A-H are perspective bottom, perspective top, top, back, bottom, side cross sectional, side, and front cross sectional views of a detector pad embodiment;

FIGS. 32A-H are perspective bottom, perspective top, top, back, bottom, side cross sectional, side, and front cross sectional views of a shoe box;

FIGS. 33A-H are perspective bottom, perspective top, top, back, bottom, side cross sectional, side, and front cross sectional views of a slim-finger emitter pad embodiment;

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FIGS. 34A-H are perspective bottom, perspective top, top, back, bottom, side cross sectional, side, and front cross sectional views of a slim-finger detector pad embodiment;

FIGS. 35A-B are plan and cross sectional views, respectively, of a spring assembly embodiment;

FIGS. 36A-C are top, perspective and side views of a finger clip spring;

FIGS. 37A-D are top, back, bottom, and side views of a spring plate;

FIGS. 38A-D are front cross sectional, bottom, front and side cross sectional views of an emitter-pad shell;

FIGS. 39A-D are back, top, front and side cross sectional views of a detector-pad shell;

FIG. 40 is a general block diagram of a monitor and a sensor;

FIGS. 41A-C are schematic diagrams of grid drive embodiments for a sensor having back-to-back diodes and an information element;

FIG. 42 is a schematic diagram of a grid drive embodiment for an information element;

FIGS. 43A-C are schematic diagrams for grid drive readable information elements;

FIGS. 44A-B are cross sectional and side cut away views of a sensor cable;

FIG. 45 is a block diagram of a sensor controller embodiment; and

FIG. 46 is a detailed exploded perspective view of a multiple wavelength sensor embodiment.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Overview

In this application, reference is made to many blood parameters. Some references that have common shorthand designations are referenced through such shorthand designations. For example, as used herein, HbCO designates carboxyhemoglobin, HbMet designates methemoglobin, and Hbt designates total hemoglobin. Other shorthand designations such as COHb, MetHb, and tHb are also common in the art for these same constituents. These constituents are generally reported in terms of a percentage, often referred to as saturation, relative concentration or fractional saturation. Total hemoglobin is generally reported as a concentration in g/dL. The use of the particular shorthand designators presented in this application does not restrict the term to any particular manner in which the designated constituent is reported.

FIG. 1 illustrates a physiological measurement system 10 having a monitor 100 and a multiple wavelength sensor assembly 200 with enhanced measurement capabilities as compared with conventional pulse oximetry. The physiological measurement system 10 allows the monitoring of a person, including a patient. In particular, the multiple wavelength sensor assembly 200 allows the measurement of blood constituent and related parameters in addition to oxygen saturation and pulse rate. Alternatively, the multiple wavelength sensor assembly 200 allows the measurement of oxygen saturation and pulse rate with increased accuracy or robustness as compared with conventional pulse oximetry.

In one embodiment, the sensor assembly 200 is configured to plug into a monitor sensor port 110. Monitor keys 160 provide control over operating modes and alarms, to name a few. A display 170 provides readouts of measured parameters, such as oxygen saturation, pulse rate, HbCO and HbMet to name a few.

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FIGS. 2A illustrates a multiple wavelength sensor assembly 200 having a sensor 400 adapted to attach to a tissue site, a sensor cable 4400 and a monitor connector 210. In one embodiment, the sensor 400 is incorporated into a reusable finger clip adapted to removably attach to, and transmit light through, a fingertip. The sensor cable 4400 and monitor connector 210 are integral to the sensor 400, as shown. In alternative embodiments, the sensor 400 may be configured separately from the cable 4400 and connector 210.

FIGS. 2B-C illustrate alternative sensor embodiments, including a sensor 401 (FIG. 2B) partially disposable and partially reusable (resposable) and utilizing an adhesive attachment mechanism. Also shown is a sensor 402 (FIG. 2C) being disposable and utilizing an adhesive attachment mechanism. In other embodiments, a sensor may be configured to attach to various tissue sites other than a finger, such as a foot or an ear. Also a sensor may be configured as a reflectance or transreflectance device that attaches to a forehead or other tissue surface.

FIG. 3 illustrates a sensor assembly 400 having an emitter assembly 500, a detector assembly 2400, an interconnect assembly 1900 and an attachment assembly 2700. The emitter assembly 500 responds to drive signals received from a sensor controller 4500 in the monitor 100 via the cable 4400 so as to transmit optical radiation having a plurality of wavelengths into a tissue site. The detector assembly 2400 provides a sensor signal to the monitor 100 via the cable 4400 in response to optical radiation received after attenuation by the tissue site. The interconnect assembly 1900 provides electrical communication between the cable 4400 and both the emitter assembly 500 and the detector assembly 2400. The attachment assembly 2700 attaches the emitter assembly 500 and detector assembly 2400 to a tissue site, as described above. The emitter assembly 500 is described in further detail with respect to FIG. 5, below. The interconnect assembly 1900 is described in further detail with respect to FIG. 19, below. The detector assembly 2400 is described in further detail with respect to FIG. 24, below. The attachment assembly 2700 is described in further detail with respect to FIG. 27, below.

FIG. 4 illustrates a sensor 400 embodiment that removably attaches to a fingertip. The sensor 400 houses a multiple wavelength emitter assembly 500 and corresponding detector assembly 2400. A flex circuit assembly 1900 mounts the emitter and detector assemblies 500, 2400 and interconnects them to a multi-wire sensor cable 4400. Advantageously, the sensor 400 is configured in several respects for both wearer comfort and parameter measurement performance. The flex circuit assembly 1900 is configured to mechanically decouple the cable 4400 wires from the emitter and detector assemblies 500, 2400 to reduce pad stiffness and wearer discomfort. The pads 3000, 3100 are mechanically decoupled from shells 3800, 3900 to increase flexibility and wearer comfort. A spring 3600 is configured in hinged shells 3800, 3900 so that the pivot point of the finger clip is well behind the fingertip, improving finger attachment and more evenly distributing the clip pressure along the finger.

As shown in FIG. 4, the detector pad 3100 is structured to properly position a fingertip in relationship to the detector assembly 2400. The pads have flaps that block ambient light. The detector assembly 2400 is housed in an enclosure so as to reduce light piping from the emitter assembly to the detector assembly without passing through fingertip tissue. These and other features are described in detail below. Specifically, emitter assembly embodiments are described with respect to FIGS. 5-18. Interconnect assembly embodiments, including the flexible circuit assembly 1900, are described with respect

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to FIGS. 19-23. Detector assembly embodiments are described with respect to FIGS. 24-26. Attachment assembly embodiments are described with respect to FIGS. 27-39.

Emitter Assembly

FIG. 5 illustrates an emitter assembly 500 having an emitter array 700, a substrate 1200 and equalization 900. The emitter array 700 has multiple light emitting sources, each activated by addressing at least one row and at least one column of an electrical grid. The light emitting sources are capable of transmitting optical radiation having multiple wavelengths. The equalization 900 accounts for differences in tissue attenuation of the optical radiation across the multiple wavelengths so as to at least reduce wavelength-dependent variations in detected intensity. The substrate 1200 provides a physical mount for the emitter array and emitter-related equalization and a connection between the emitter array and the interconnection assembly. Advantageously, the substrate 1200 also provides a bulk temperature measurement so as to calculate the operating wavelengths for the light emitting sources. The emitter array 700 is described in further detail with respect to FIG. 7, below. Equalization is described in further detail with respect to FIG. 9, below. The substrate 1200 is described in further detail with respect to FIG. 12, below.

FIG. 6 illustrates an emitter assembly 500 embodiment having an emitter array 700, an encapsulant 600, an optical filter 1100 and a substrate 1200. Various aspects of the emitter assembly 500 are described with respect to FIGS. 7-18, below. The emitter array 700 emits optical radiation having multiple wavelengths of predetermined nominal values, advantageously allowing multiple parameter measurements. In particular, the emitter array 700 has multiple light emitting diodes (LEDs) 710 that are physically arranged and electrically connected in an electrical grid to facilitate drive control, equalization, and minimization of optical pathlength differences at particular wavelengths. The optical filter 1100 is advantageously configured to provide intensity equalization across a specific LED subset. The substrate 1200 is configured to provide a bulk temperature of the emitter array 700 so as to better determine LED operating wavelengths.

Emitter Array

FIG. 7 illustrates an emitter array 700 having multiple light emitters (LE) 710 capable of emitting light 702 having multiple wavelengths into a tissue site 1. Row drivers 4530 and column drivers 4560 are electrically connected to the light emitters 710 and activate one or more light emitters 710 by addressing at least one row 720 and at least one column 740 of an electrical grid. In one embodiment, the light emitters 710 each include a first contact 712 and a second contact 714. The first contact 712 of a first subset 730 of light emitters is in communication with a first conductor 720 of the electrical grid. The second contact 714 of a second subset 750 of light emitters is in communication with a second conductor 740. Each subset comprises at least two light emitters, and at least one of the light emitters of the first and second subsets 730, 750 are not in common. A detector 2400 is capable of detecting the emitted light 702 and outputting a sensor signal 2500 responsive to the emitted light 702 after attenuation by the tissue site 1. As such, the sensor signal 2500 is indicative of at least one physiological parameter corresponding to the tissue site 1, as described above.

FIG. 8 illustrates an emitter array 700 having LEDs 801 connected within an electrical grid of n rows and m columns totaling n+m drive lines 4501, 4502, where n and m integers greater than one. The electrical grid advantageously minimizes the number of drive lines required to activate the LEDs

801 while preserving flexibility to selectively activate individual LEDs **801** in any sequence and multiple LEDs **801** simultaneously. The electrical grid also facilitates setting LED currents so as to control intensity at each wavelength, determining operating wavelengths and monitoring total grid current so as to limit power dissipation. The emitter array **700** is also physically configured in rows **810**. This physical organization facilitates clustering LEDs **801** according to wavelength so as to minimize pathlength variations and facilitates equalization of LED intensities.

As shown in FIG. 8, one embodiment of an emitter array **700** comprises up to sixteen LEDs **801** configured in an electrical grid of four rows **810** and four columns **820**. Each of the four row drive lines **4501** provide a common anode connection to four LEDs **801**, and each of the four column drive lines **4502** provide a common cathode connection to four LEDs **801**. Thus, the sixteen LEDs **801** are advantageously driven with only eight wires, including four anode drive lines **812** and four cathode drive lines **822**. This compares favorably to conventional common anode or cathode LED configurations, which require more drive lines. In a particular embodiment, the emitter array **700** is partially populated with eight LEDs having nominal wavelengths as shown in TABLE 1. Further, LEDs having wavelengths in the range of 610-630 nm are grouped together in the same row. The emitter array **700** is adapted to a physiological measurement system **10** (FIG. 1) for measuring H_bCO and/or $METHb$ in addition to S_pO_2 and pulse rate.

TABLE 1

LED	Nominal LED Wavelengths		
	λ	Row	Col
D1	630	1	1
D2	620	1	2
D3	610	1	3
D4		1	4
D5	700	2	1
D6	730	2	2
D7	660	2	3
D8	805	2	4
D9		3	1
D10		3	2
D11		3	3
D12	905	3	4
D13		4	1
D14		4	2
D15		4	3
D16		4	4

Also shown in FIG. 8, row drivers **4530** and column drivers **4560** located in the monitor **100** selectively activate the LEDs **801**. In particular, row and column drivers **4530**, **4560** function together as switches to Vcc and current sinks, respectively, to activate LEDs and as switches to ground and Vcc, respectively, to deactivate LEDs. This push-pull drive configuration advantageously prevents parasitic current flow in deactivated LEDs. In a particular embodiment, only one row drive line **4501** is switched to Vcc at a time. One to four column drive lines **4502**, however, can be simultaneously switched to a current sink so as to simultaneously activate multiple LEDs within a particular row. Activation of two or more LEDs of the same wavelength facilitates intensity equalization, as described with respect to FIGS. 9-11, below. LED drivers are described in further detail with respect to FIG. 45, below.

Although an emitter assembly is described above with respect to an array of light emitters each configured to trans-

mit optical radiation centered around a nominal wavelength, in another embodiment, an emitter assembly advantageously utilizes one or more tunable broadband light sources, including the use of filters to select the wavelength, so as to minimize wavelength-dependent pathlength differences from emitter to detector. In yet another emitter assembly embodiment, optical radiation from multiple emitters each configured to transmit optical radiation centered around a nominal wavelength is funneled to a tissue site point so as to minimize wavelength-dependent pathlength differences. This funneling may be accomplished with fiberoptics or mirrors, for example. In further embodiments, the LEDs **801** can be configured with alternative orientations with correspondingly different drivers among various other configurations of LEDs, drivers and interconnecting conductors.

Equalization

FIG. 9 illustrate a physiological parameter measurement system **10** having a controller **4500**, an emitter assembly **500**, a detector assembly **2400** and a front-end **4030**. The emitter assembly **500** is configured to transmit optical radiation having multiple wavelengths into the tissue site **1**. The detector assembly **2400** is configured to generate a sensor signal **2500** responsive to the optical radiation after tissue attenuation. The front-end **4030** conditions the sensor signal **2500** prior to analog-to-digital conversion (ADC).

FIG. 9 also generally illustrates equalization **900** in a physiological measurement system **10** operating on a tissue site **1**. Equalization encompasses features incorporated into the system **10** in order to provide a sensor signal **2500** that falls well within the dynamic range of the ADC across the entire spectrum of emitter wavelengths. In particular, equalization compensates for the imbalance in tissue light absorption due to Hb and HbO_2 **910**. Specifically, these blood constituents attenuate red wavelengths greater than IR wavelengths. Ideally, equalization **900** balances this unequal attenuation. Equalization **900** can be introduced anywhere in the system **10** from the controller **4500** to front-end **4000** and can include compensatory attenuation versus wavelength, as shown, or compensatory amplification versus or both.

Equalization can be achieved to a limited extent by adjusting drive currents from the controller **4500** and front-end **4030** amplification accordingly to wavelength so as to compensate for tissue absorption characteristics. Signal demodulation constraints, however, limit the magnitude of these adjustments. Advantageously, equalization **900** is also provided along the optical path from emitters **500** to detector **2400**. Equalization embodiments are described in further detail with respect to FIGS. 10-11, below.

FIGS. 10A-D illustrate various equalization embodiments having an emitter array **700** adapted to transmit optical radiation into a tissue site **1** and a detector assembly **2400** adapted to generate a sensor signal **2500** responsive to the optical radiation after tissue attenuation. FIG. 10A illustrates an optical filter **1100** that attenuates at least a portion of the optical radiation before it is transmitted into a tissue site **1**. In particular, the optical filter **1100** attenuates at least a portion of the IR wavelength spectrum of the optical radiation so as to approximate an equalization curve **900** (FIG. 9). FIG. 10B illustrates an optical filter **1100** that attenuates at least a portion of the optical radiation after it is attenuated by a tissue site **1**, where the optical filter **1100** approximates an equalization curve **900** (FIG. 9).

FIG. 10C illustrates an emitter array **700** where at least a portion of the emitter array generates one or more wavelengths from multiple light emitters **710** of the same wavelength. In particular, the same-wavelength light emitters **710** boost at least a portion of the red wavelength spectrum so as

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to approximately equalize the attenuation curves **910** (FIG. **9**). FIG. **10D** illustrates a detector assembly **2400** having multiple detectors **2610**, **2620** selected so as to equalize the attenuation curves **910** (FIG. **9**). To a limited extent, optical equalization can also be achieved by selection of particular emitter array **700** and detector **2400** components, e.g. LEDs having higher output intensities or detectors having higher sensitivities at red wavelengths. Although equalization embodiments are described above with respect to red and IR wavelengths, these equalization embodiments can be applied to equalize tissue characteristics across any portion of the optical spectrum.

FIGS. **11A-C** illustrates an optical filter **1100** for an emitter assembly **500** that advantageously provides optical equalization, as described above. LEDs within the emitter array **700** may be grouped according to output intensity or wavelength or both. Such a grouping facilitates equalization of LED intensity across the array. In particular, relatively low tissue absorption and/or relatively high output intensity LEDs can be grouped together under a relatively high attenuation optical filter. Likewise, relatively low tissue absorption and/or relatively low output intensity LEDs can be grouped together without an optical filter or under a relatively low or negligible attenuation optical filter. Further, high tissue absorption and/or low intensity LEDs can be grouped within the same row with one or more LEDs of the same wavelength being simultaneously activated, as described with respect to FIG. **10C**, above. In general, there can be any number of LED groups and any number of LEDs within a group. There can also be any number of optical filters corresponding to the groups having a range of attenuation, including no optical filter and/or a "clear" filter having negligible attenuation.

As shown in FIGS. **11A-C**, a filtering media may be advantageously added to an encapsulant that functions both as a cover to protect LEDs and bonding wires and as an optical filter **1100**. In one embodiment, a filtering media **1100** encapsulates a select group of LEDs and a clear media **600** (FIG. **6**) encapsulates the entire array **700** and the filtering media **1000** (FIG. **6**). In a particular embodiment, corresponding to TABLE 1, above, five LEDs nominally emitting at 660-905 nm are encapsulated with both a filtering media **1100** and an overlying clear media **600** (FIG. **6**), i.e. attenuated. In a particular embodiment, the filtering media **1100** is a 40:1 mixture of a clear encapsulant (EPO-TEK OG147-7) and an opaque encapsulate (EPO-TEK OG147) both available from Epoxy Technology, Inc., Billerica, Mass. Three LEDs nominally emitting at 610-630 nm are only encapsulated with the clear media **600** (FIG. **6**), i.e. unattenuated. In alternative embodiments, individual LEDs may be singly or multiply encapsulated according to tissue absorption and/or output intensity. In other alternative embodiments, filtering media may be separately attachable optical filters or a combination of encapsulants and separately attachable optical filters. In a particular embodiment, the emitter assembly **500** has one or more notches along each side proximate the component end **1305** (FIG. **13**) for retaining one or more clip-on optical filters.

Substrate

FIG. **12** illustrates light emitters **710** configured to transmit optical radiation **1201** having multiple wavelengths in response to corresponding drive currents **1210**. A thermal mass **1220** is disposed proximate the emitters **710** so as to stabilize a bulk temperature **1202** for the emitters. A temperature sensor **1230** is thermally coupled to the thermal mass **1220**, wherein the temperature sensor **1230** provides a temperature sensor output **1232** responsive to the bulk temperature **1202** so that the wavelengths are determinable as a function of the drive currents **1210** and the bulk temperature **1202**.

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In one embodiment, an operating wavelength λ_a of each light emitter **710** is determined according to EQ. 3

$$\lambda_a = f(T_b, I_{drive}, \sum I_{drive}) \quad (3)$$

where T_b is the bulk temperature, I_{drive} is the drive current for a particular light emitter, as determined by the sensor controller **4500** (FIG. **45**), described below, and $\sum I_{drive}$ is the total drive current for all light emitters. In another embodiment, temperature sensors are configured to measure the temperature of each light emitter **710** and an operating wavelength λ_a of each light emitter **710** is determined according to EQ. 4

$$\lambda_a = f(T_a, I_{drive}, \sum I_{drive}) \quad (4)$$

where T_a is the temperature of a particular light emitter, I_{drive} is the drive current for that light emitter and $\sum I_{drive}$ is the total drive current for all light emitters.

In yet another embodiment, an operating wavelength for each light emitter is determined by measuring the junction voltage for each light emitter **710**. In a further embodiment, the temperature of each light emitter **710** is controlled, such as by one or more Peltier cells coupled to each light emitter **710**, and an operating wavelength for each light emitter **710** is determined as a function of the resulting controlled temperature or temperatures. In other embodiments, the operating wavelength for each light emitter **710** is determined directly, for example by attaching a charge coupled device (CCD) to each light emitter or by attaching a fiberoptic to each light emitter and coupling the fiberoptics to a wavelength measuring device, to name a few.

FIGS. **13-18** illustrate one embodiment of a substrate **1200** configured to provide thermal conductivity between an emitter array **700** (FIG. **8**) and a thermistor **1540** (FIG. **16**). In this manner, the resistance of the thermistor **1540** (FIG. **16**) can be measured in order to determine the bulk temperature of LEDs **801** (FIG. **8**) mounted on the substrate **1200**. The substrate **1200** is also configured with a relatively significant thermal mass, which stabilizes and normalizes the bulk temperature so that the thermistor measurement of bulk temperature is meaningful.

FIGS. **13-14** illustrate a substrate **1200** having a component side **1301**, a solder side **1302**, a component end **1305** and a connector end **1306**. Alignment notches **1310** are disposed between the ends **1305**, **1306**. The substrate **1200** further has a component layer **1401**, inner layers **1402-1405** and a solder layer **1406**. The inner layers **1402-1405**, e.g. inner layer **1402** (FIG. **18**), have substantial metallized areas **1411** that provide a thermal mass **1220** (FIG. **12**) to stabilize a bulk temperature for the emitter array **700** (FIG. **12**). The metallized areas **1411** also function to interconnect component pads **1510** and wire bond pads **1520** (FIG. **15**) to the connector **1530**.

FIGS. **15-16** illustrate a substrate **1200** having component pads **1510** and wire bond pads **1520** at a component end **1305**. The component pads **1510** mount and electrically connect a first side (anode or cathode) of the LEDs **801** (FIG. **8**) to the substrate **1200**. Wire bond pads **1520** electrically connect a second side (cathode or anode) of the LEDs **801** (FIG. **8**) to the substrate **1200**. The connector end **1306** has a connector **1530** with connector pads **1532**, **1534** that mount and electrically connect the emitter assembly **500** (FIG. **23**), including the substrate **1200**, to the flex circuit **2200** (FIG. **22**). Sub-

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strate layers **1401-1406** (FIG. **14**) have traces that electrically connect the component pads **1510** and wire bond pads **1520** to the connector **1532-1534**. A thermistor **1540** is mounted to thermistor pads **1550** at the component end **1305**, which are also electrically connected with traces to the connector **1530**. Plated thru holes electrically connect the connector pads **1532, 1534** on the component and solder sides **1301, 1302**, respectively.

FIG. **17** illustrates the electrical layout of a substrate **1200**. A portion of the LEDs **801**, including **D1-D4** and **D13-D16** have cathodes physically and electrically connected to component pads **1510** (FIG. **15**) and corresponding anodes wire bonded to wire bond pads **1520**. Another portion of the LEDs **801**, including **D5-D8** and **D9-D12**, have anodes physically and electrically connected to component pads **1510** (FIG. **15**) and corresponding cathodes wire bonded to wire bond pads **1520**. The connector **1530** has row pinouts **J21-J24**, column pinouts **J31-J34** and thermistor pinouts **J40-J41** for the LEDs **801** and thermistor **1540**.

Interconnect Assembly

FIG. **19** illustrates an interconnect assembly **1900** that mounts the emitter assembly **500** and detector assembly **2400**, connects to the sensor cable **4400** and provides electrical communications between the cable and each of the emitter assembly **500** and detector assembly **2400**. In one embodiment, the interconnect assembly **1900** is incorporated with the attachment assembly **2700**, which holds the emitter and detector assemblies to a tissue site. An interconnect assembly embodiment utilizing a flexible (flex) circuit is described with respect to FIGS. **20-24**, below.

FIG. **20** illustrates an interconnect assembly **1900** embodiment having a circuit substrate **2200**, an emitter mount **2210**, a detector mount **2220** and a cable connector **2230**. The emitter mount **2210**, detector mount **2220** and cable connector **2230** are disposed on the circuit substrate **2200**. The emitter mount **2210** is adapted to mount an emitter assembly **500** having multiple emitters. The detector mount **2220** is adapted to mount a detector assembly **2400** having a detector. The cable connector **2230** is adapted to attach a sensor cable **4400**. A first plurality of conductors **2040** disposed on the circuit substrate **2200** electrically interconnects the emitter mount **2210** and the cable connector **2230**. A second plurality of conductors **2050** disposed on the circuit substrate **2200** electrically interconnects the detector mount **2220** and the cable connector **2230**. A decoupling **2060** disposed proximate the cable connector **2230** substantially mechanically isolates the cable connector **2230** from both the emitter mount **2210** and the detector mount **2220** so that sensor cable stiffness is not translated to the emitter assembly **500** or the detector assembly **2400**. A shield **2070** is adapted to fold over and shield one or more wires or pairs of wires of the sensor cable **4400**.

FIG. **21** illustrates a flex circuit assembly **1900** having a flex circuit **2200**, an emitter assembly **500** and a detector assembly **2400**, which is configured to terminate the sensor end of a sensor cable **4400**. The flex circuit assembly **1900** advantageously provides a structure that electrically connects yet mechanically isolates the sensor cable **4400**, the emitter assembly **500** and the detector assembly **2400**. As a result, the mechanical stiffness of the sensor cable **4400** is not translated to the sensor pads **3000, 3100** (FIGS. **30-31**), allowing a comfortable finger attachment for the sensor **200** (FIG. **1**). In particular, the emitter assembly **500** and detector assembly **2400** are mounted to opposite ends **2201, 2202** (FIG. **22**) of an elongated flex circuit **2200**. The sensor cable **4400** is mounted to a cable connector **2230** extending from a middle portion of the flex circuit **2200**. Detector wires **4470** are shielded at the

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flex circuit junction by a fold-over conductive ink flap **2240**, which is connected to a cable inner shield **4450**. The flex circuit **2200** is described in further detail with respect to FIG. **22**. The emitter portion of the flex circuit assembly **1900** is described in further detail with respect to FIG. **23**. The detector assembly **2400** is described with respect to FIG. **24**. The sensor cable **4400** is described with respect to FIGS. **44A-B**, below.

FIG. **22** illustrates a sensor flex circuit **2200** having an emitter end **2201**, a detector end **2202**, an elongated interconnect **2204, 2206** between the ends **2201, 2202** and a cable connector **2230** extending from the interconnect **2204, 2206**. The emitter end **2201** forms a "head" having emitter solder pads **2210** for attaching the emitter assembly **500** (FIG. **6**) and mounting ears **2214** for attaching to the emitter pad **3000** (FIG. **30B**), as described below. The detector end **2202** has detector solder pads for attaching the detector **2410** (FIG. **24**). The interconnect **2204** between the emitter end **2201** and the cable connector **2230** forms a "neck," and the interconnect **2206** between the detector end **2202** and the cable connector **2230** forms a "tail." The cable connector **2230** forms "wings" that extend from the interconnect **2204, 2206** between the neck **2204** and tail **2206**. A conductive ink flap **2240** connects to the cable inner shield **4450** (FIGS. **44A-B**) and folds over to shield the detector wires **4470** (FIGS. **44A-B**) soldered to the detector wire pads **2236**. The outer wire pads **2238** connect to the remaining cable wires **4430** (FIGS. **44A-B**). The flex circuit **2200** has top coverlay, top ink, inner coverlay, trace, trace base, bottom ink and bottom coverlay layers.

The flex circuit **2200** advantageously provides a connection between a multiple wire sensor cable **4400** (FIGS. **44A-B**), a multiple wavelength emitter assembly **500** (FIG. **6**) and a detector assembly **2400** (FIG. **24**) without rendering the emitter and detector assemblies unwieldy and stiff. In particular, the wings **2230** provide a relatively large solder pad area **2232** that is narrowed at the neck **2204** and tail **2206** to mechanically isolate the cable **4400** (FIGS. **44A-B**) from the remainder of the flex circuit **2200**. Further, the neck **2206** is folded (see FIG. **4**) for installation in the emitter pad **3000** (FIGS. **30A-H**) and acts as a flexible spring to further mechanically isolate the cable **4400** (FIGS. **44A-B**) from the emitter assembly **500** (FIG. **4**). The tail **2206** provides an integrated connectivity path between the detector assembly **2400** (FIG. **24**) mounted in the detector pad **3100** (FIGS. **31A-H**) and the cable connector **2230** mounted in the opposite emitter pad **3000** (FIGS. **30A-H**).

FIG. **23** illustrates the emitter portion of the flex circuit assembly **1900** (FIG. **21**) having the emitter assembly **500**. The emitter assembly connector **1530** is attached to the emitter end **2210** of the flex circuit **2200** (FIG. **22**). In particular, reflow solder **2330** connects thru hole pads **1532, 1534** of the emitter assembly **500** to corresponding emitter pads **2310** of the flex circuit **2200** (FIG. **22**).

FIG. **24** illustrates a detector assembly **2400** including a detector **2410**, solder pads **2420**, copper mesh tape **2430**, an EMI shield **2440** and foil **2450**. The detector **2410** is soldered **2460** chip side down to detector solder pads **2420** of the flex circuit **2200**. The detector solder joint and detector ground pads **2420** are wrapped with the Kapton tape **2470**. EMI shield tabs **2442** are folded onto the detector pads **2420** and soldered. The EMI shield walls are folded around the detector **2410** and the remaining tabs **2442** are soldered to the back of the EMI shield **2440**. The copper mesh tape **2430** is cut to size and the shielded detector and flex circuit solder joint are wrapped with the copper mesh tape **2430**. The foil **2450** is cut to size with a predetermined aperture **2452**. The foil **2450** is

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wrapped around shielded detector with the foil side in and the aperture 2452 is aligned with the EMI shield grid 2444.

Detector Assembly

FIG. 25 illustrates an alternative detector assembly 2400 embodiment having adjacent detectors. Optical radiation having multiple wavelengths generated by emitters 700 is transmitted into a tissue site 1. Optical radiation at a first set of wavelengths is detected by a first detector 2510, such as, for example, a Si detector. Optical radiation at a second set of wavelengths is detected by a second detector 2520, such as, for example, a GaAs detector.

FIG. 26 illustrates another alternative detector assembly 2400 embodiment having stacked detectors coaxial along a light path. Optical radiation having multiple wavelengths generated by emitters 700 is transmitted into a tissue site 1. Optical radiation at a first set of wavelengths is detected by a first detector 2610. Optical radiation at a second set of wavelengths passes through the first detector 2610 and is detected by a second detector 2620. In a particular embodiment, a silicon (Si) detector and a gallium arsenide (GaAs) detector are used. The Si detector is placed on top of the GaAs detector so that light must pass through the Si detector before reaching the GaAs detector. The Si detector can be placed directly on top of the GaAs detector or the Si and GaAs detector can be separated by some other medium, such as a transparent medium or air. In another particular embodiment, a germanium detector is used instead of the GaAs detector. Advantageously, the stacked detector arrangement minimizes error caused by pathlength differences as compared with the adjacent detector embodiment.

Finger Clip

FIG. 27 illustrates a finger clip embodiment 2700 of a physiological sensor attachment assembly. The finger clip 2700 is configured to removably attach an emitter assembly 500 (FIG. 6) and detector assembly 2400 (FIG. 24), interconnected by a flex circuit assembly 1900, to a fingertip. The finger clip 2700 has an emitter shell 3800, an emitter pad 3000, a detector pad 2800 and a detector shell 3900. The emitter shell 3800 and the detector shell 3900 are rotatably connected and urged together by the spring assembly 3500. The emitter pad 3000 is fixedly retained by the emitter shell. The emitter assembly 500 (FIG. 6) is mounted proximate the emitter pad 3000 and adapted to transmit optical radiation having a plurality of wavelengths into fingertip tissue. The detector pad 2800 is fixedly retained by the detector shell 3900. The detector assembly 3500 is mounted proximate the detector pad 2800 and adapted to receive the optical radiation after attenuation by fingertip tissue.

FIG. 28 illustrates a detector pad 2800 advantageously configured to position and comfortably maintain a fingertip relative to a detector assembly for accurate sensor measurements. In particular, the detector pad has fingertip positioning features including a guide 2810, a contour 2820 and a stop 2830. The guide 2810 is raised from the pad surface 2803 and narrows as the guide 2810 extends from a first end 2801 to a second end 2802 so as to increasingly conform to a fingertip as a fingertip is inserted along the pad surface 2803 from the first end 2801. The contour 2820 has an indentation defined along the pad surface 2803 generally shaped to conform to a fingertip positioned over a detector aperture 2840 located within the contour 2820. The stop 2830 is raised from the pad surface 2803 so as to block the end of a finger from inserting beyond the second end 2802. FIGS. 29A-B illustrate detector pad embodiments 3100, 3400 each having a guide 2810, a contour 2820 and a stop 2830, described in further detail with respect to FIGS. 31 and 34, respectively.

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FIGS. 30A-H illustrate an emitter pad 3000 having emitter pad flaps 3010, an emitter window 3020, mounting pins 3030, an emitter assembly cavity 3040, isolation notches 3050, a flex circuit notch 3070 and a cable notch 3080. The emitter pad flaps 3010 overlap with detector pad flaps 3110 (FIGS. 31A-H) to block ambient light. The emitter window 3020 provides an optical path from the emitter array 700 (FIG. 8) to a tissue site. The mounting pins 3030 accommodate apertures in the flex circuit mounting ears 2214 (FIG. 22), and the cavity 3040 accommodates the emitter assembly 500 (FIG. 21). Isolation notches 3050 mechanically decouple the shell attachment 3060 from the remainder of the emitter pad 3000. The flex circuit notch 3070 accommodates the flex circuit tail 2206 (FIG. 22) routed to the detector pad 3100 (FIGS. 31A-H). The cable notch 3080 accommodates the sensor cable 4400 (FIGS. 44A-B). FIGS. 33A-H illustrate an alternative slim finger emitter pad 3300 embodiment.

FIGS. 31A-H illustrate a detector pad 3100 having detector pad flaps 3110, a shoe box cavity 3120 and isolation notches 3150. The detector pad flaps 3110 overlap with emitter pad flaps 3010 (FIGS. 30A-H), interleaving to block ambient light. The shoe box cavity 3120 accommodates a shoe box 3200 (FIG. 32A-H) described below. Isolation notches 3150 mechanically decouple the attachment points 3160 from the remainder of the detector pad 3100. FIGS. 34A-H illustrate an alternative slim finger detector pad 3400 embodiment.

FIGS. 32A-H illustrate a shoe box 3200 that accommodates the detector assembly 2400 (FIG. 24). A detector window 3210 provides an optical path from a tissue site to the detector 2410 (FIG. 24). A flex circuit notch 3220 accommodates the flex circuit tail 2206 (FIG. 22) routed from the emitter pad 3000 (FIGS. 30A-H). In one embodiment, the shoe box 3200 is colored black or other substantially light absorbing color and the emitter pad 3000 and detector pad 3100 are each colored white or other substantially light reflecting color.

FIGS. 35-37 illustrate a spring assembly 3500 having a spring 3600 configured to urge together an emitter shell 3800 (FIG. 46) and a detector shell 3900. The detector shell is rotatably connected to the emitter shell. The spring is disposed between the shells 3800, 3900 and adapted to create a pivot point along a finger gripped between the shells that is substantially behind the fingertip. This advantageously allows the shell hinge 3810, 3910 (FIGS. 38-39) to expand so as to distribute finger clip force along the inserted finger, comfortably keeping the fingertip in position over the detector without excessive force.

As shown in FIGS. 36A-C, the spring 3600 has coils 3610, an emitter shell leg 3620 and a detector shell leg 3630. The emitter shell leg 3620 presses against the emitter shell 3800 (FIGS. 38A-D) proximate a grip 3820 (FIGS. 38A-D). The detector shell legs 3630 extend along the detector shell 3900 (FIGS. 39A-D) to a spring plate 3700 (FIGS. 37A-D) attachment point. The coil 3610 is secured by hinge pins 410 (FIG. 46) and is configured to wind as the finger clip is opened, reducing its diameter and stress accordingly.

As shown in FIGS. 37A-D the spring plate 3700 has attachment apertures 3710, spring leg slots 3720, and a shelf 3730. The attachment apertures 3710 accept corresponding shell posts 3930 (FIGS. 39A-D) so as to secure the spring plate 3700 to the detector shell 3900 (FIG. 39A-D). Spring legs 3630 (FIG. 36A-C) are slidably anchored to the detector shell 3900 (FIG. 39A-D) by the shelf 3730, advantageously allowing the combination of spring 3600, shells 3800, 3900 and hinges 3810, 3910 to adjust to various finger sizes and shapes.

FIGS. 38-39 illustrate the emitter and detector shells 3800, 3900, respectively, having hinges 3810, 3910 and grips 3820,

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3920. Hinge apertures 3812, 3912 accept hinge pins 410 (FIG. 46) so as to create a finger clip. The detector shell hinge aperture 3912 is elongated, allowing the hinge to expand to accommodate a finger.

Monitor and Sensor

FIG. 40 illustrates a monitor 100 and a corresponding sensor assembly 200, as described generally with respect to FIGS. 1-3, above. The sensor assembly 200 has a sensor 400 and a sensor cable 4400. The sensor 400 houses an emitter assembly 500 having emitters responsive to drivers within a sensor controller 4500 so as to transmit optical radiation into a tissue site. The sensor 400 also houses a detector assembly 2400 that provides a sensor signal 2500 responsive to the optical radiation after tissue attenuation. The sensor signal 2500 is filtered, amplified, sampled and digitized by the front-end 4030 and input to a DSP (digital signal processor) 4040, which also commands the sensor controller 4500. The sensor cable 4400 electrically communicates drive signals from the sensor controller 4500 to the emitter assembly 500 and a sensor signal 2500 from the detector assembly 2400 to the front-end 4030. The sensor cable 4400 has a monitor connector 210 that plugs into a monitor sensor port 110.

In one embodiment, the monitor 100 also has a reader 4020 capable of obtaining information from an information element (IE) in the sensor assembly 200 and transferring that information to the DSP 4040, to another processor or component within the monitor 100, or to an external component or device that is at least temporarily in communication with the monitor 100. In an alternative embodiment, the reader function is incorporated within the DSP 4040, utilizing one or more of DSP I/O, ADC, DAC features and corresponding processing routines, as examples.

In one embodiment, the monitor connector 210 houses the information element 4000, which may be a memory device or other active or passive electrical component. In a particular embodiment, the information element 4000 is an EPROM, or other programmable memory, or an EEPROM, or other reprogrammable memory, or both. In an alternative embodiment, the information element 4000 is housed within the sensor 400, or an information element 4000 is housed within both the monitor connector 4000 and the sensor 400. In yet another embodiment, the emitter assembly 500 has an information element 4000, which is read in response to one or more drive signals from the sensor controller 4500, as described with respect to FIGS. 41-43, below. In a further embodiment, a memory information element is incorporated into the emitter array 700 (FIG. 8) and has characterization information relating to the LEDs 801 (FIG. 8). In one advantageous embodiment, trend data relating to slowly varying parameters, such as perfusion index, HbCO or METHb, to name a few, are stored in an IE memory device, such as EEPROM.

Back-To-Back LEDs

FIGS. 41-43 illustrate alternative sensor embodiments. A sensor controller 4500 configured to activate an emitter array 700 (FIG. 7) arranged in an electrical grid, is described with respect to FIG. 7, above. Advantageously, a sensor controller 4500 so configured is also capable of driving a conventional two-wavelength (red and IR) sensor 4100 having back-to-back LEDs 4110, 4120 or an information element 4300 or both.

FIG. 41A illustrates a sensor 4100 having an electrical grid 4130 configured to activate light emitting sources by addressing at least one row conductor and at least one column conductor. A first LED 4110 and a second LED 4120 are configured in a back-to-back arrangement so that a first contact 4152 is connected to a first LED 4110 cathode and a second LED

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4120 anode and a second contact 4154 is connected to a first LED 4110 anode and a second LED 4120 cathode. The first contact 4152 is in communications with a first row conductor 4132 and a first column conductor 4134. The second contact 4154 is in communications with a second row conductor 4136 and a second column conductor 4138. The first LED 4110 is activated by addressing the first row conductor 4132 and the second column conductor 4138. The second LED 4120 is activated by addressing the second row conductor 4136 and the first column conductor 4134.

FIG. 41B illustrates a sensor cable 4400 embodiment capable of communicating signals between a monitor 100 and a sensor 4100. The cable 4400 has a first row input 4132, a first column input 4134, a second row input 4136 and a second column input 4138. A first output 4152 combines the first row input 4132 and the first column input 4134. A second output 4154 combines a second row input 4136 and second column input 4138.

FIG. 41C illustrates a monitor 100 capable of communicating drive signals to a sensor 4100. The monitor 4400 has a first row signal 4132, a first column signal 4134, a second row signal 4136 and a second column signal 4138. A first output signal 4152 combines the first row signal 4132 and the first column signal 4134. A second output signal 4154 combines a second row signal 4136 and second column signal 4138.

Information Elements

FIGS. 42-43 illustrate information element 4200-4300 embodiments in communications with emitter array drivers configured to activate light emitters connected in an electrical grid. The information elements are configured to provide information as DC values, AC values or a combination of DC and AC values in response corresponding DC, AC or combination DC and AC electrical grid drive signals. FIG. 42 illustrates information element embodiment 4200 advantageously driven directly by an electrical grid having rows 710 and columns 720. In particular, the information element 4200 has a series connected resistor R_2 4210 and diode 4220 connected between a row line 710 and a column line 720 of an electrical grid. In this manner, the resistor R_2 value can be read in a similar manner that LEDs 810 (FIG. 8) are activated. The diode 4220 is oriented, e.g. anode to row and cathode to column as the LEDs so as to prevent parasitic currents from unwanted activation of LEDs 810 (FIG. 8).

FIGS. 43A-C illustrate other embodiments where the value of R_1 is read with a DC grid drive current and a corresponding grid output voltage level. In other particular embodiments, the combined values of R_1 , R_2 and C or, alternatively, R_1 , R_2 and L are read with a varying (AC) grid drive currents and a corresponding grid output voltage waveform. As one example, a step in grid drive current is used to determine component values from the time constant of a corresponding rise in grid voltage. As another example, a sinusoidal grid drive current is used to determine component values from the magnitude or phase or both of a corresponding sinusoidal grid voltage. The component values determined by DC or AC electrical grid drive currents can represent sensor types, authorized suppliers or manufacturers, emitter wavelengths among others. Further, a diode D (FIG. 43C) can be used to provide one information element reading R_1 at one drive level or polarity and another information element reading, combining R_1 and R_2 , at a second drive level or polarity, i.e. when the diode is forward biased.

Passive information element 4300 embodiments may include any of various combinations of resistors, capacitors or inductors connected in series and parallel, for example. Other information element 4300 embodiments connected to an electrical grid and read utilizing emitter array drivers

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incorporate other passive components, active components or memory components, alone or in combination, including transistor networks, PROMs, ROMs, EPROMs, EEPROMs, gate arrays and PLAs to name a few.

Sensor Cable

FIGS. 44A-B illustrate a sensor cable 4400 having an outer jacket 4410, an outer shield 4420, multiple outer wires 4430, an inner jacket 4440, an inner shield 4450, a conductive polymer 4460 and an inner twisted wire pair 4470. The outer wires 4430 are advantageously configured to compactly carry multiple drive signals to the emitter array 700 (FIG. 7). In one embodiment, there are twelve outer wires 4430 corresponding to four anode drive signals 4501 (FIG. 45), four cathode drive signals 4502 (FIG. 45), two thermistor pinouts 1450 (FIG. 15) and two spares. The inner twisted wire pair 4470 corresponds to the sensor signal 2500 (FIG. 25) and is extruded within the conductive polymer 4460 so as to reduce triboelectric noise. The shields 4420, 4450 and the twisted pair 4470 boost EMI and crosstalk immunity for the sensor signal 2500 (FIG. 25).

Controller

FIG. 45 illustrates a sensor controller 4500 located in the monitor 100 (FIG. 1) and configured to provide anode drive signals 4501 and cathode drive signals 4502 to the emitter array 700 (FIG. 7). The DSP (digital signal processor) 4040, which performs signal processing functions for the monitor, also provides commands 4042 to the sensor controller 4500. These commands determine drive signal 4501, 4502 levels and timing. The sensor controller 4500 has a command register 4510, an anode selector 4520, anode drivers 4530, current DACs (digital-to-analog converters) 4540, a current multiplexer 4550, cathode drivers 4560, a current meter 4570 and a current limiter 4580. The command register 4510 provides control signals responsive to the DSP commands 4042. In one embodiment, the command register 4510 is a shift register that loads serial command data 4042 from the DSP 4040 and synchronously sets output bits that select or enable various functions within the sensor controller 4500, as described below.

As shown in FIG. 45, the anode selector 4520 is responsive to anode select 4516 inputs from the command register 4510 that determine which emitter array row 810 (FIG. 8) is active. Accordingly, the anode selector 4520 sets one of the anode on 4522 outputs to the anode drivers 4530, which pulls up to Vcc one of the anode outputs 4501 to the emitter array 700 (FIG. 8).

Also shown in FIG. 45, the current DACs 4540 are responsive to command register data 4519 that determines the currents through each emitter array column 820 (FIG. 8). In one embodiment, there are four, 12-bit DACs associated with each emitter array column 820 (FIG. 8), sixteen DACs in total. That is, there are four DAC outputs 4542 associated with each emitter array column 820 (FIG. 8) corresponding to the currents associated with each row 810 (FIG. 8) along that column 820 (FIG. 8). In a particular embodiment, all sixteen DACs 4540 are organized as a single shift register, and the command register 4510 serially clocks DAC data 4519 into the DACs 4540. A current multiplexer 4550 is responsive to cathode on 4518 inputs from the command register 4510 and anode on 4522 inputs from the anode selector 4520 so as to convert the appropriate DAC outputs 4542 to current set 4552 inputs to the cathode drivers 4560. The cathode drivers 4560 are responsive to the current set 4552 inputs to pull down to ground one to four of the cathode outputs 4502 to the emitter array 700 (FIG. 8).

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The current meter 4570 outputs a current measure 4572 that indicates the total LED current driving the emitter array 700 (FIG. 8). The current limiter 4580 is responsive to the current measure 4572 and limits specified by the command register 4510 so as to prevent excessive power dissipation by the emitter array 700 (FIG. 8). The current limiter 4580 provides an enable 4582 output to the anode selector 4520. A Hi Limit 4512 input specifies the higher of two preset current limits. The current limiter 4580 latches the enable 4582 output in an off condition when the current limit is exceeded, disabling the anode selector 4520. A trip reset 4514 input resets the enable 4582 output to re-enable the anode selector 4520.

Sensor Assembly

As shown in FIG. 46, the sensor 400 has an emitter shell 3800, an emitter pad 3000, a flex circuit assembly 2200, a detector pad 3100 and a detector shell 3900. A sensor cable 4400 attaches to the flex circuit assembly 2200, which includes a flex circuit 2100, an emitter assembly 500 and a detector assembly 2400. The portion of the flex circuit assembly 2200 having the sensor cable 4400 attachment and emitter assembly 500 is housed by the emitter shell 3800 and emitter pad 3000. The portion of the flex circuit assembly 2200 having the detector assembly 2400 is housed by the detector shell 3900 and detector pad 3100. In particular, the detector assembly 2400 inserts into a shoe 3200, and the shoe 3200 inserts into the detector pad 3100. The emitter shell 3800 and detector shell 3900 are fastened by and rotate about hinge pins 410, which insert through coils of a spring 3600. The spring 3600 is held to the detector shell 3900 with a spring plate 3700. A finger stop 450 attaches to the detector shell. In one embodiment, a silicon adhesive 420 is used to attach the pads 3000, 3100 to the shells 3800, 3900, a silicon potting compound 430 is used to secure the emitter and detector assemblies 500, 2400 within the pads 3000, 3100, and a cyanoacrylic adhesive 440 secures the sensor cable 4400 to the emitter shell 3800.

A multiple wavelength sensor has been disclosed in detail in connection with various embodiments. These embodiments are disclosed by way of examples only and are not to limit the scope of the claims that follow. One of ordinary skill in art will appreciate many variations and modifications.

What is claimed is:

1. A physiological sensor configured to measure an indication of a physiological characteristic of a living patient, the physiological sensor comprising:

a plurality of light emitting sources arranged to impinge light on body tissue of a living patient, each light emitting source activated by addressing at least one of a plurality of rows and at least one of a plurality of columns of an electrical grid, the light emitting sources capable of transmitting light of a plurality of wavelengths, wherein there are fewer light emitting sources than intersections of the rows and columns;

a detector responsive to the transmitted light after attenuation by body tissue of the living patient, the body tissue including pulsating blood, wherein the detector is configured to generate a signal indicative of a physiological characteristic of the living patient; and

a sensor housing configured to position the plurality of light emitting sources and the detector with respect to the body tissue of the living patient.

2. The physiological sensor according to claim 1 wherein multiple ones of the light emitting sources are capable of transmitting light of the same wavelength, the multiple ones simultaneously activated by addressing one of the rows.

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3. The physiological sensor according to claim 2 wherein: the light emitting sources are LEDs, and each of the LEDs have an anode in common with one of the rows and a cathode in common with one of the columns so that driving one of the rows and one of the columns activates a unique one of the LEDs.

4. The physiological sensor according to claim 3 further comprising:
a plurality of row drivers in communication with the rows; and
a plurality of column drivers in communication with the columns,
wherein a selected row driver sources current to a corresponding row and selected column driver sinks current from a corresponding column so as to activate an addressed one of the LEDs.

5. The physiological sensor according to claim 4 wherein deselected ones of the row drivers pull corresponding rows to a low voltage via a functional switch configured to operably connect deselected rows to a low voltage source and deselected ones of the column drivers pull corresponding columns to a high voltage via a functional switch configured to operably connect deselected columns to a high voltage source so as to substantially block parasitic current from unaddressed ones of the LEDs.

6. The physiological sensor according to claim 5 wherein the electrical grid comprises at least three rows or at least three columns.

7. The physiological sensor according to claim 5 wherein the electrical grid communicates with at least eight LEDs.

8. The physiological sensor of claim 1, wherein the plurality of light emitting sources and the detector are coupled to a flex circuit.

9. The physiological sensor of claim 1, wherein the plurality of light emitting sources are arranged to minimize optical pathlength differences.

10. The physiological sensor of claim 1, wherein the plurality of light emitting sources are arranged to facilitate equalization.

11. The physiological sensor of claim 1, wherein the electrical grid is arranged so as to prevent parasitic currents from unwanted activation of the light emitting sources.

12. The physiological sensor of claim 1, wherein the light emitting sources correspond to multiple different wavelengths of light, the light sources being arranged in clusters corresponding to said wavelengths.

13. The physiological sensor of claim 12, wherein the light sources are arranged in clusters corresponding to said wavelengths so as to minimize pathlength variations.

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14. The physiological sensor of claim 12, wherein the light sources are arranged in clusters corresponding to said wavelengths so as to facilitate equalization of intensities.

15. The physiological sensor of claim 12, wherein the light emitting sources are further configured to comprise wavelengths usable to measure two or more of HbCO, METHb, and SpO₂.

16. A method for measuring a physiological characteristic of a living patient, the method comprising:
positioning a sensor with respect to body tissue of a living patient, the sensor comprising a plurality of light emitting sources arranged to impinge light on the body tissue and a detector, the light emitting sources being arranged in an electrical grid comprising rows and columns, wherein there are fewer light emitting sources than intersections of the rows and columns;
activating the plurality of light emitting sources, said activating each light emitting source comprising addressing at least one of the rows and at least one of the columns of the electrical grid, such that a plurality of wavelengths of light are emitted from the plurality of light emitting sources;
detecting the light with the detector after attenuation by the body tissue of the living patient, the body tissue comprising pulsating blood; and
generating a signal reflecting a physiological characteristic of the living patient responsive to the detected light.

17. The method of claim 16, wherein the electrical grid is arranged so as to prevent parasitic currents from unwanted activation of the light emitting sources.

18. The method of claim 16, further comprising connecting deselected columns to a voltage source to substantially block parasitic current from unaddressed ones of the light emitting sources.

19. The method of claim 16, wherein the light emitting sources correspond to multiple different wavelengths of light, the light sources being arranged in clusters corresponding to said wavelengths.

20. The method of claim 19, wherein the light sources are arranged in said clusters corresponding to said wavelengths so as to minimize pathlength variations.

21. The method of claim 19, wherein the light sources are arranged in said clusters corresponding to said wavelengths so as to facilitate equalization of intensities.

22. The method of claim 16, wherein the light emitting sources are further configured to emit wavelengths adapted to measure two or more of HbCO, METHb, and SpO₂.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 7,764,982 B2
APPLICATION NO. : 11/367013
DATED : July 27, 2010
INVENTOR(S) : Smith et al.

Page 1 of 1

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

On the Title Page, Item (12) "Dalke et al." should read --Smith et al.--

On the Title Page, Item (75) Inventors: should read --Robert Smith, Lake Forest, CA (US); David Dalke, Irvine, CA (US); Ammar Al-Ali, Tustin, CA (US); Mohamed Diab, Mission Viejo, CA (US); Marcelo Lamago, Rancho Santa Margarita, CA (US)--

Signed and Sealed this
Twenty-eighth Day of February, 2012

A handwritten signature in black ink that reads "David J. Kappos". The signature is written in a cursive, flowing style.

David J. Kappos
Director of the United States Patent and Trademark Office

EXHIBIT 6

(19) **United States**

(12) **Patent Application Publication**

Al-Ali et al.

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(43) **Pub. Date: Jun. 27, 2002**

(54) **STEREO PULSE OXIMETER**

(52) **U.S. Cl. 600/323**

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Mohamed K. Diab, Mission Viejo, CA (US); **Massi E. Kiani**, Laguna Niguel, CA (US); **Robert James Kopotic**, Jamul, CA (US); **David Tobler**, Westminster, CO (US)

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(21) Appl. No.: **10/026,013**
(22) Filed: **Dec. 21, 2001**

Related U.S. Application Data

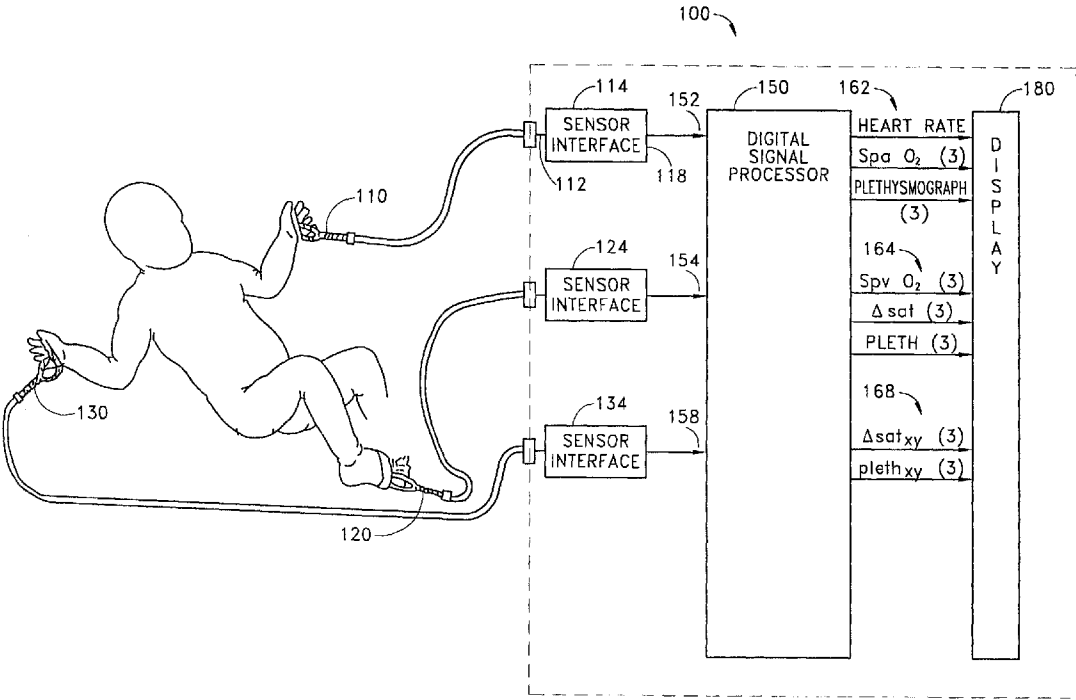
(63) Continuation of application No. 09/323,176, filed on May 27, 1999, now patented, which is a non-provisional of provisional application No. 60/087,802, filed on Jun. 3, 1998.

Publication Classification

(51) **Int. Cl.⁷ A61B 5/00**

(57) **ABSTRACT**

An improved pulse oximeter provides for simultaneous, noninvasive oxygen status and photoplethysmograph measurements at both single and multiple sites. In particular, this multiple-site, multiple-parameter pulse oximeter, or “stereo pulse oximeter” simultaneously measures both arterial and venous oxygen saturation at any specific site and generates a corresponding plethysmograph waveform. A corresponding computation of arterial minus venous oxygen saturation is particularly advantageous for oxygen therapy management. An active pulse-inducing mechanism having a scattering-limited drive generates a consistent pulsatile venous signal utilized for the venous blood measurements. The stereo pulse oximeter also measures arterial oxygen saturation and plethysmograph shape parameters across multiple sites. A corresponding calculation of delta arterial saturation and comparison of plethysmograph shape parameters between multiple sites is particularly advantageous for the detection and management of persistent pulmonary hypertension in neonates (PPHN), a patent ductus arteriosis (PDA), and aortic coarctation.



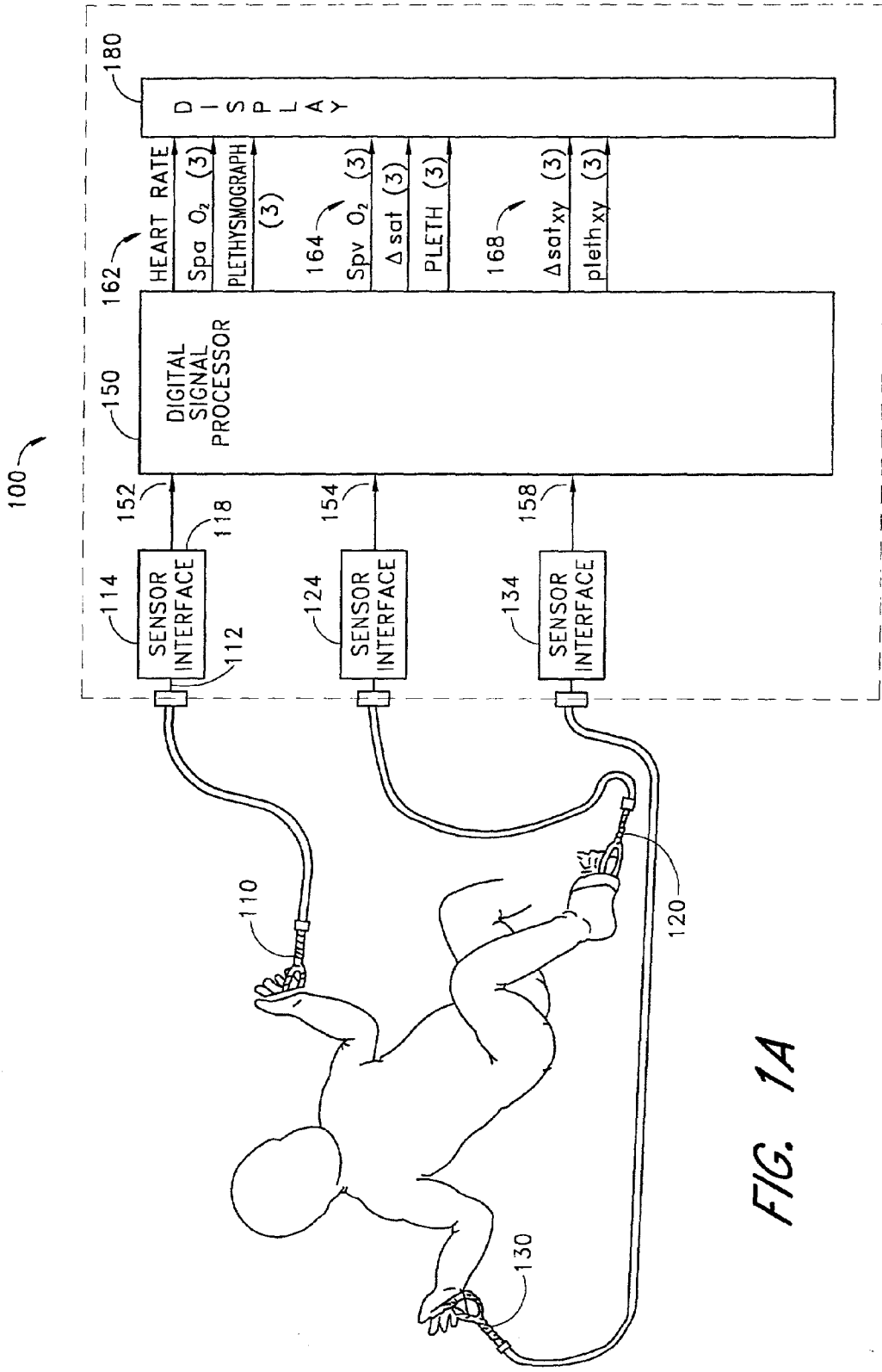
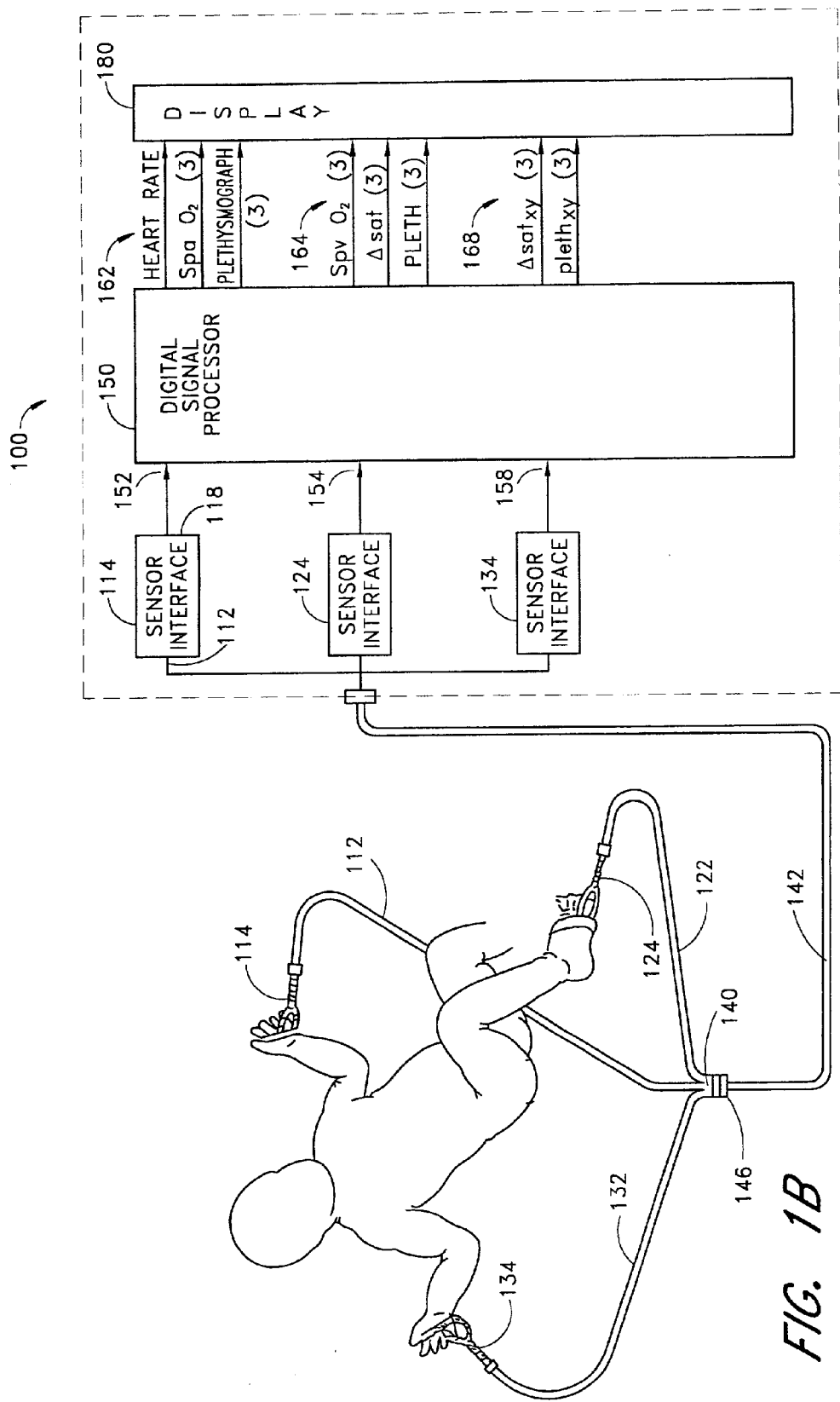


FIG. 1A



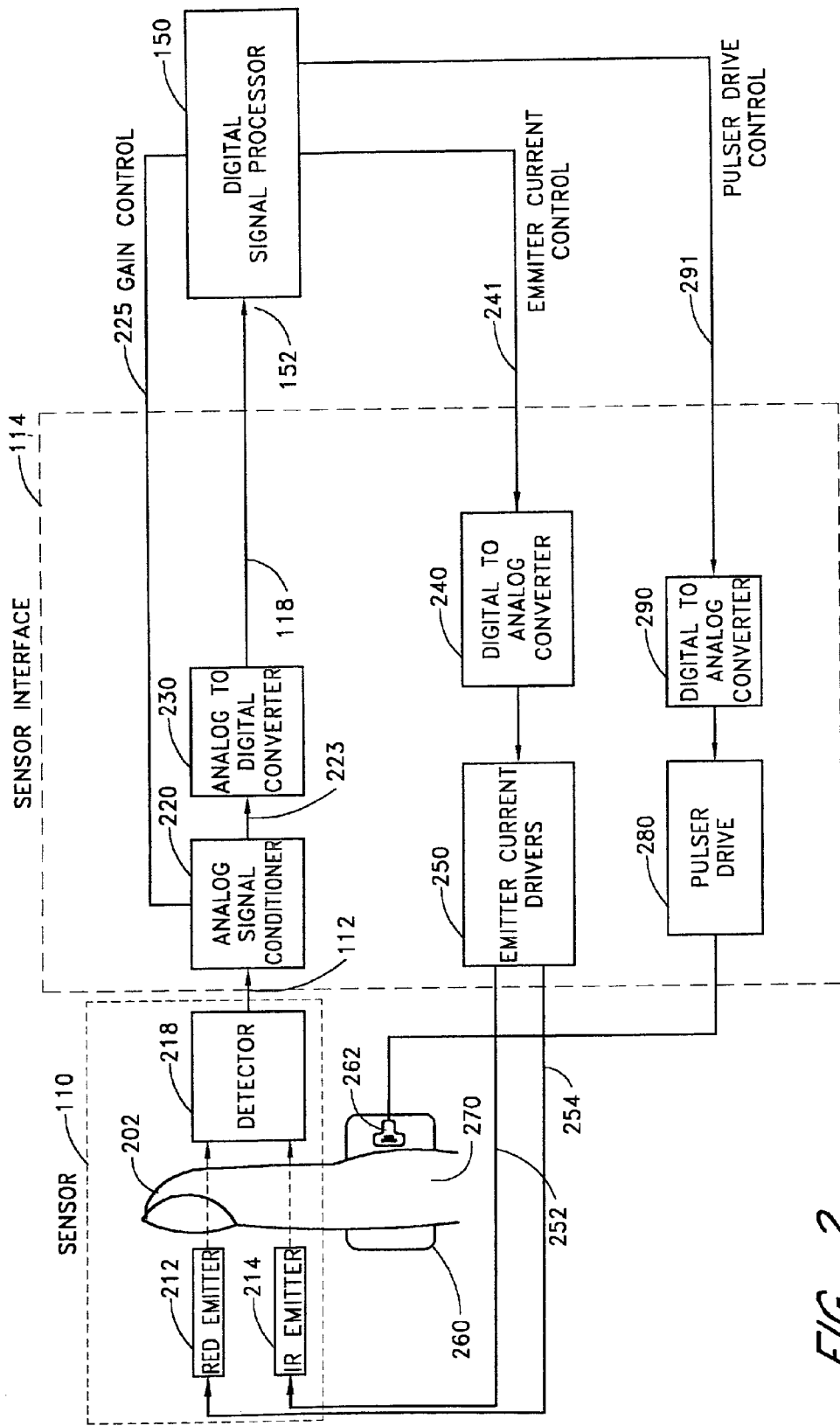


FIG. 2

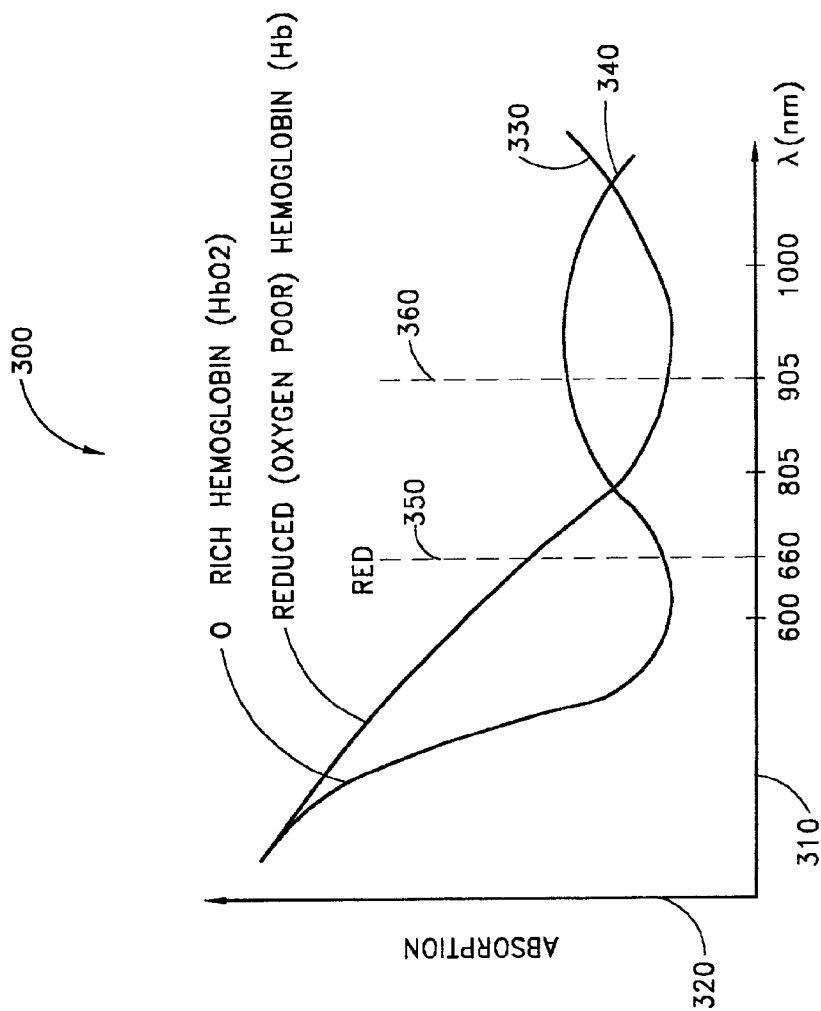


FIG. 3

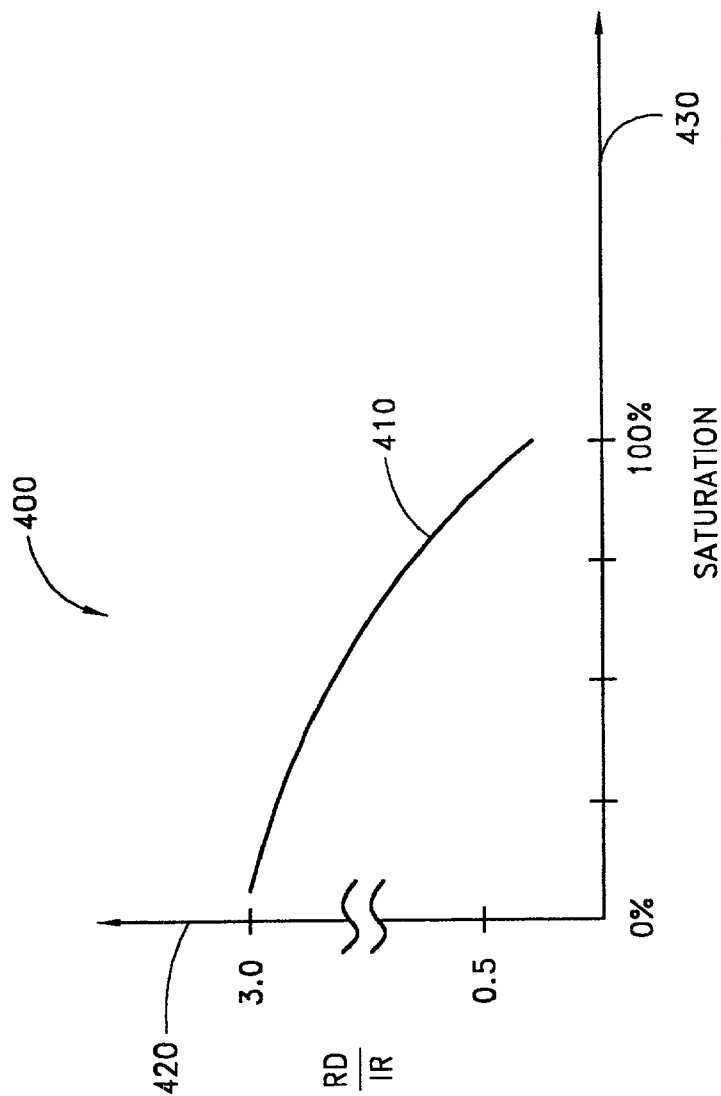


FIG. 4

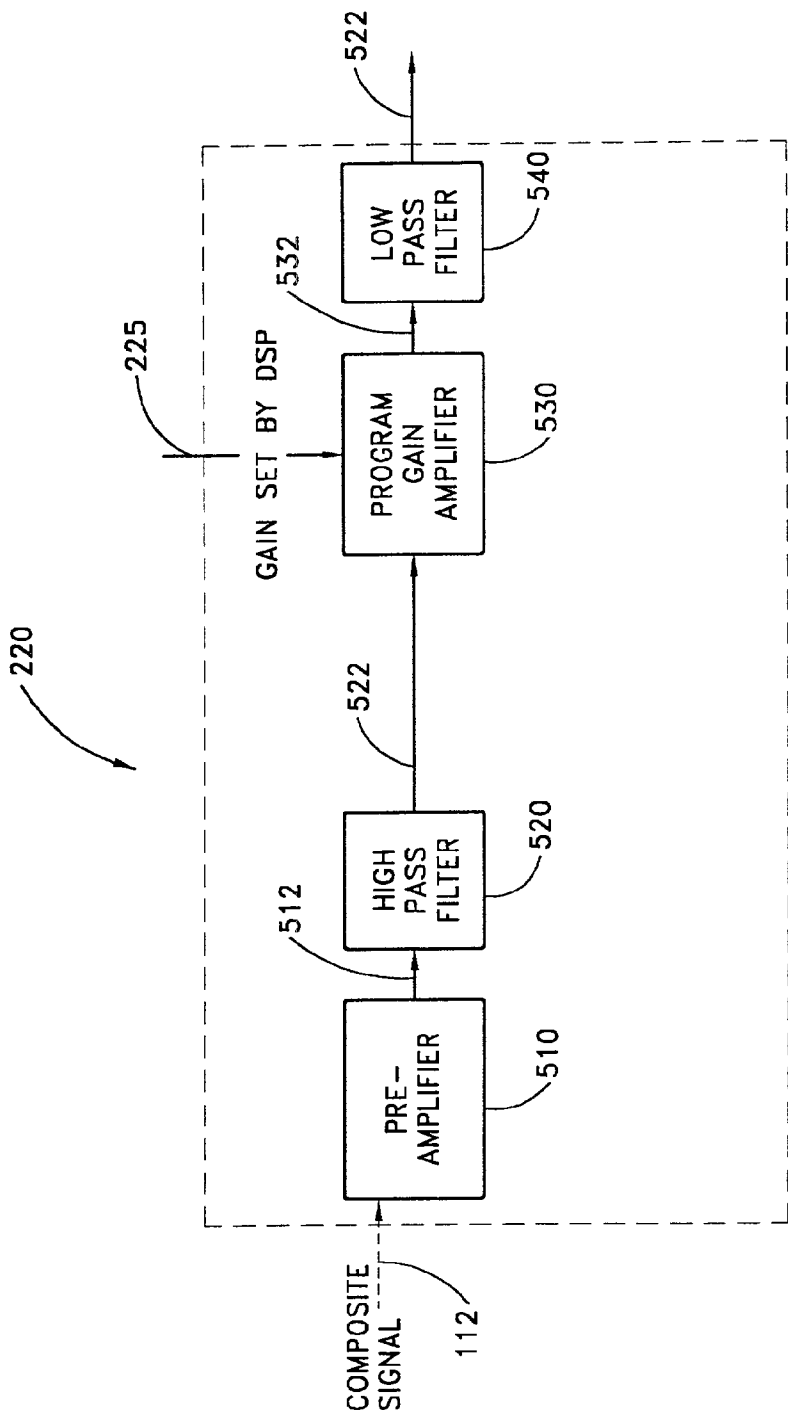


FIG. 5

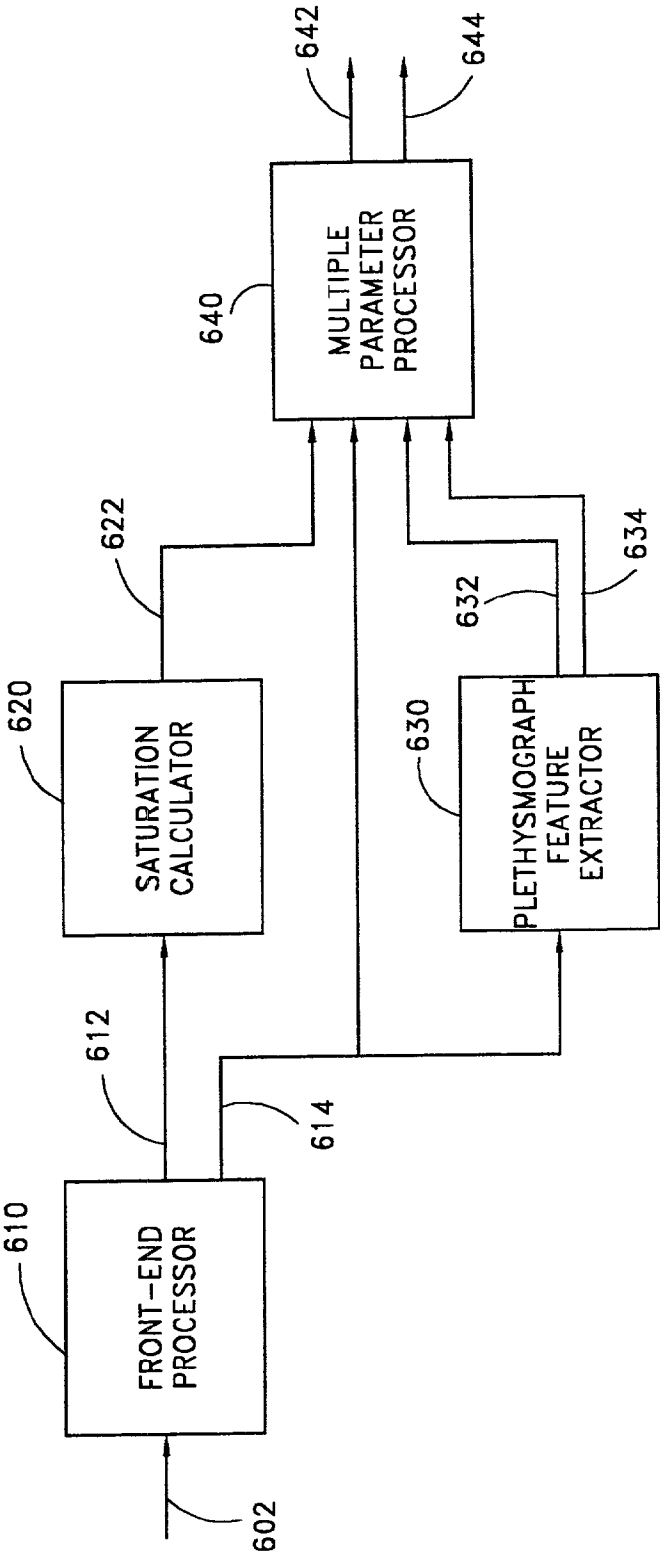


FIG. 6

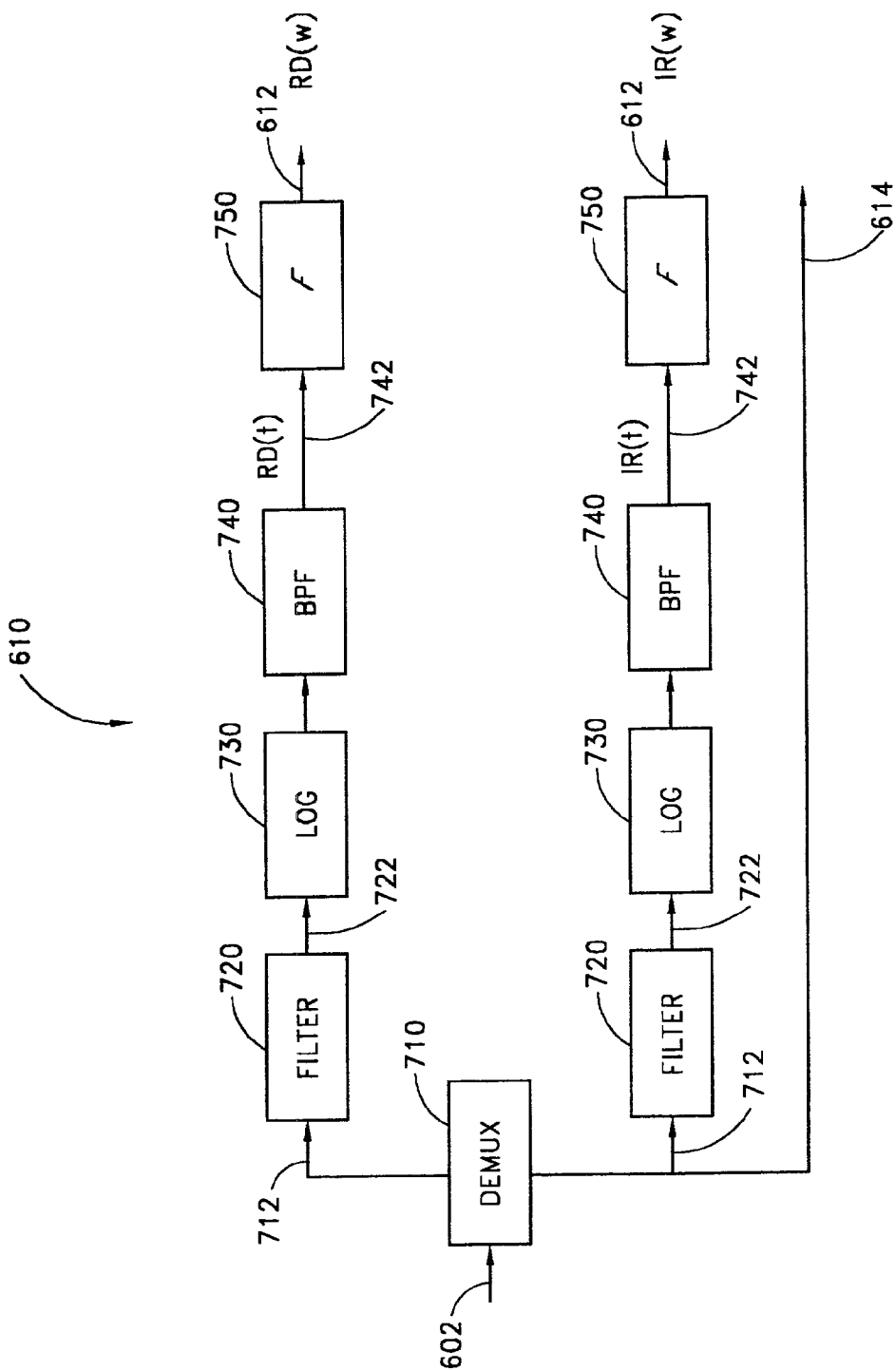


FIG. 7

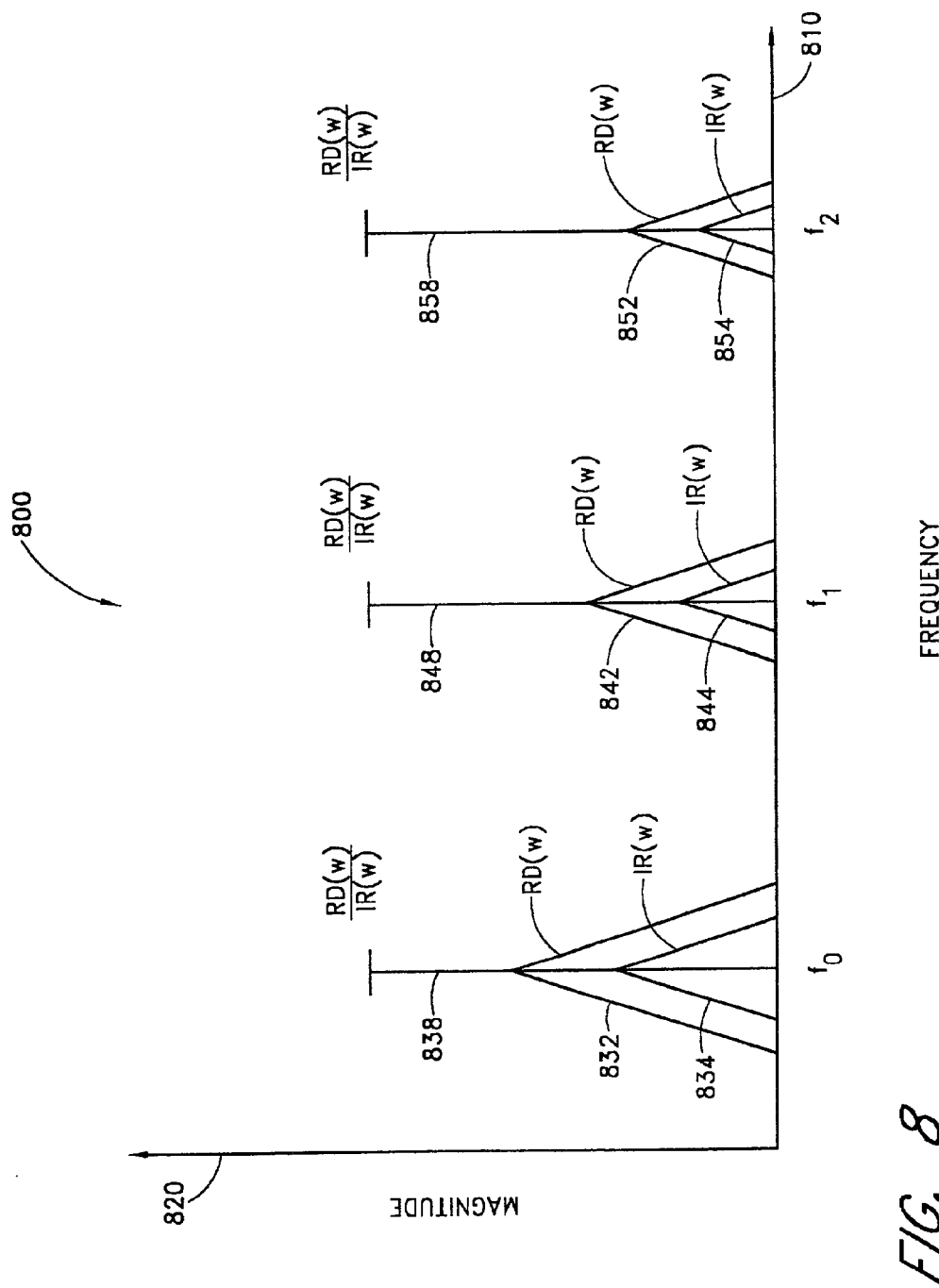


FIG. 8

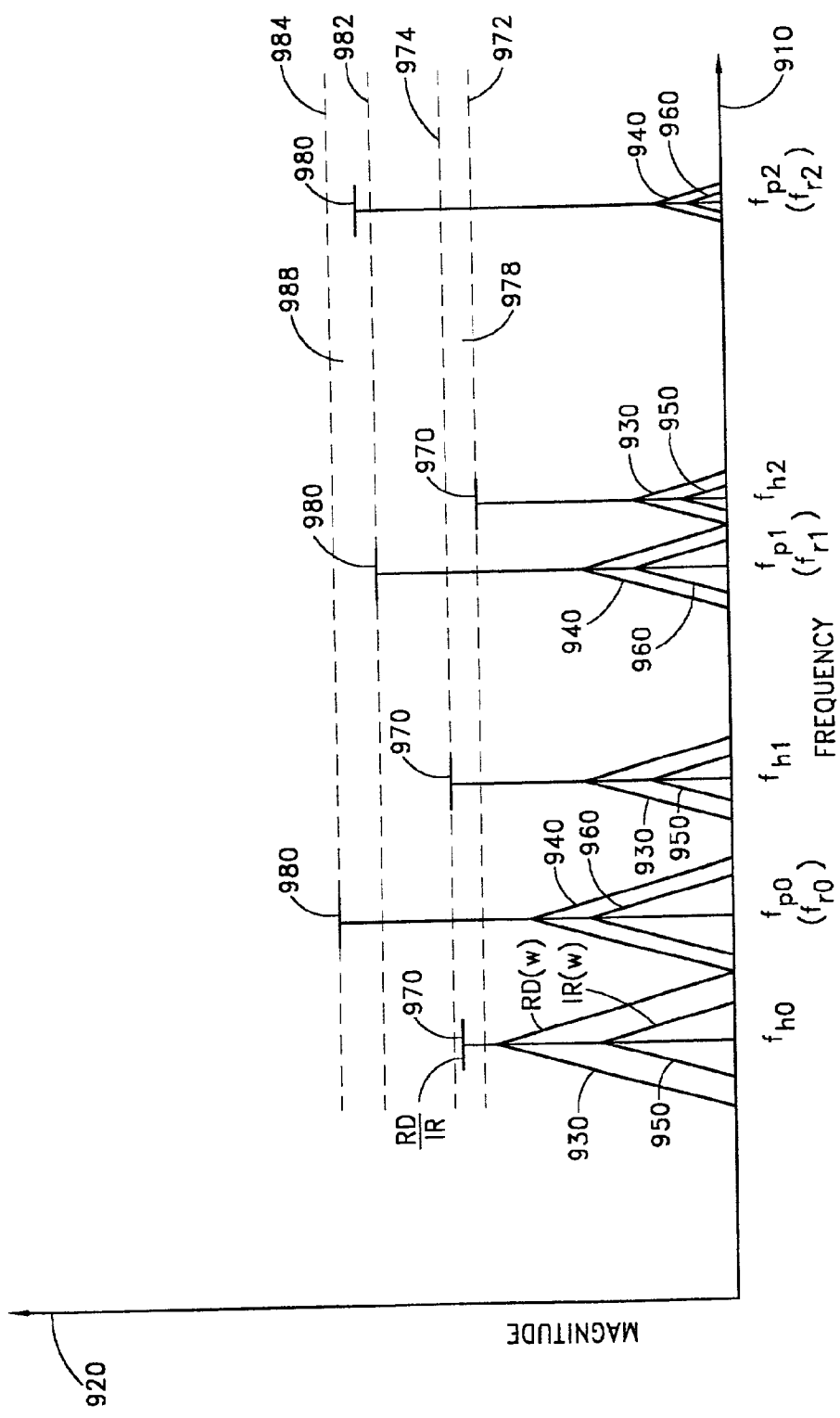


FIG. 9

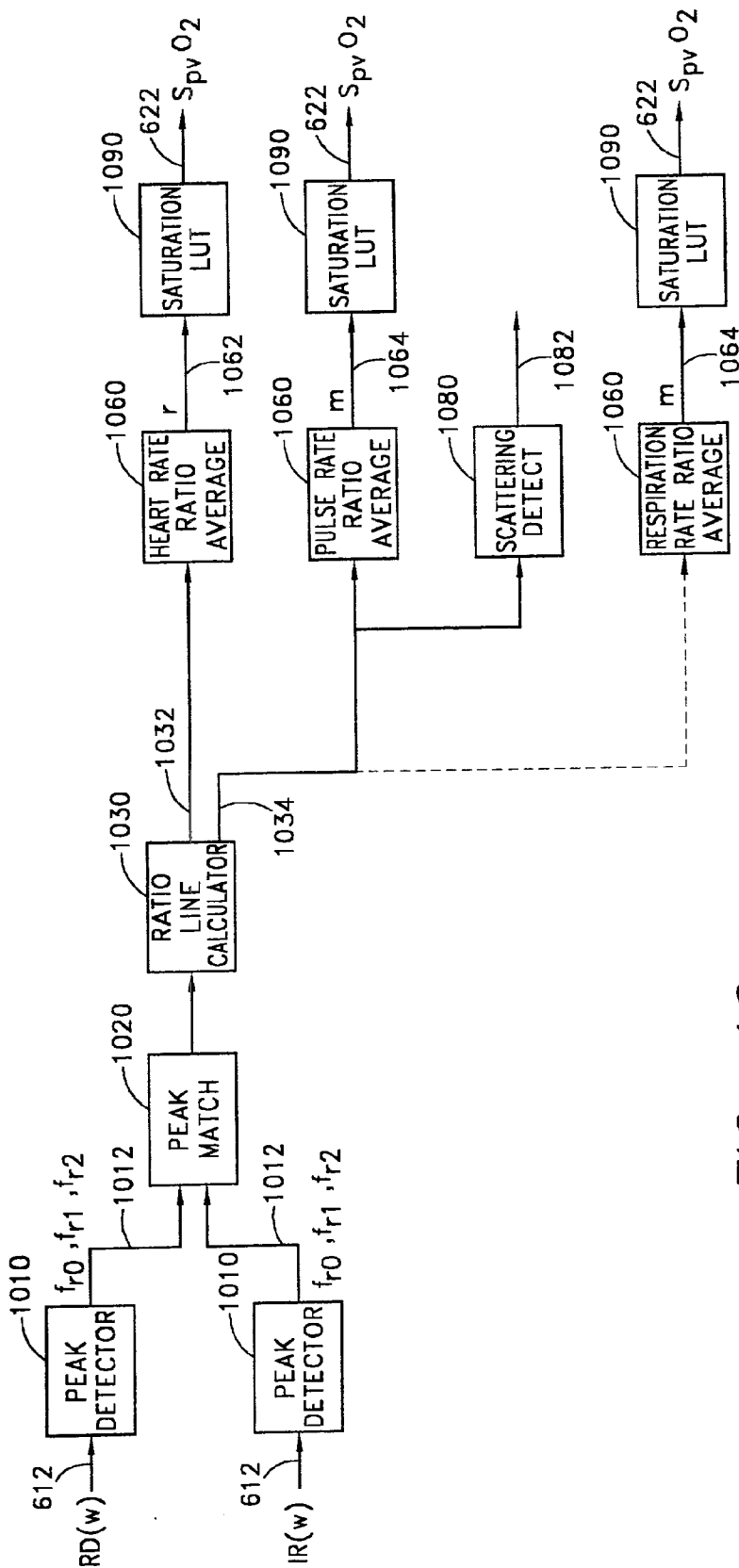


FIG. 10

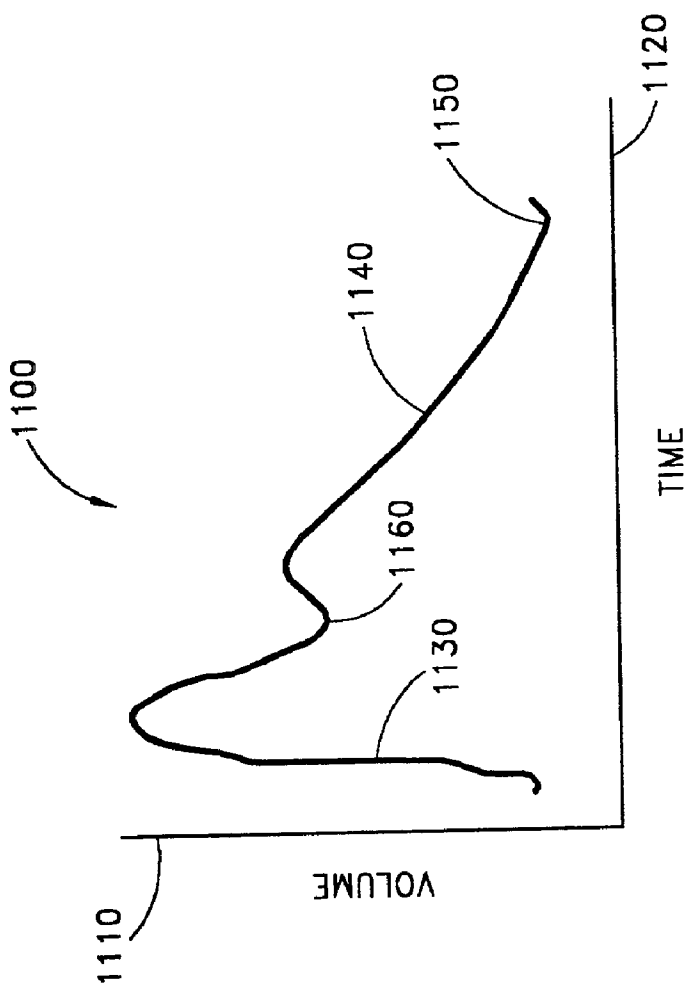


FIG. 11

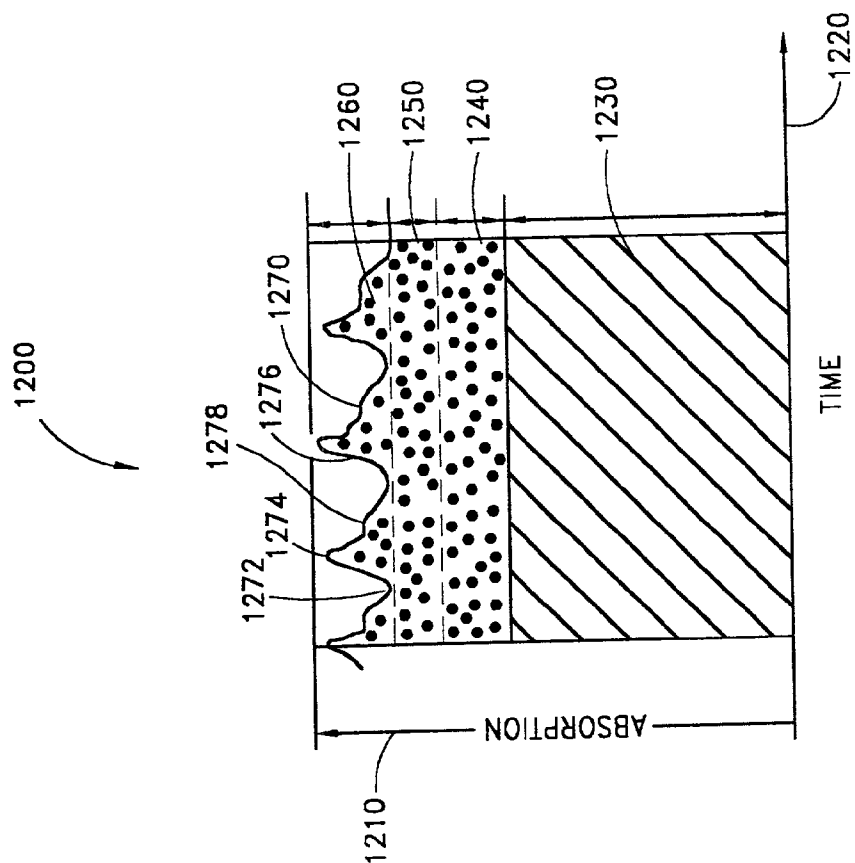


FIG. 12

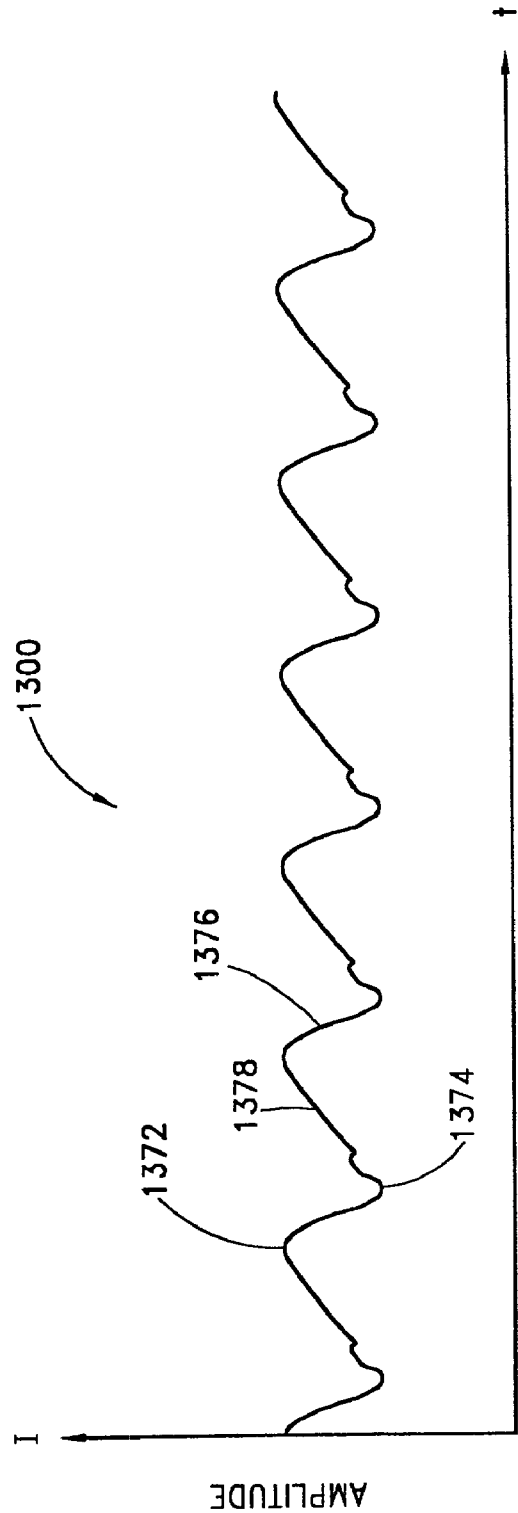


FIG. 13

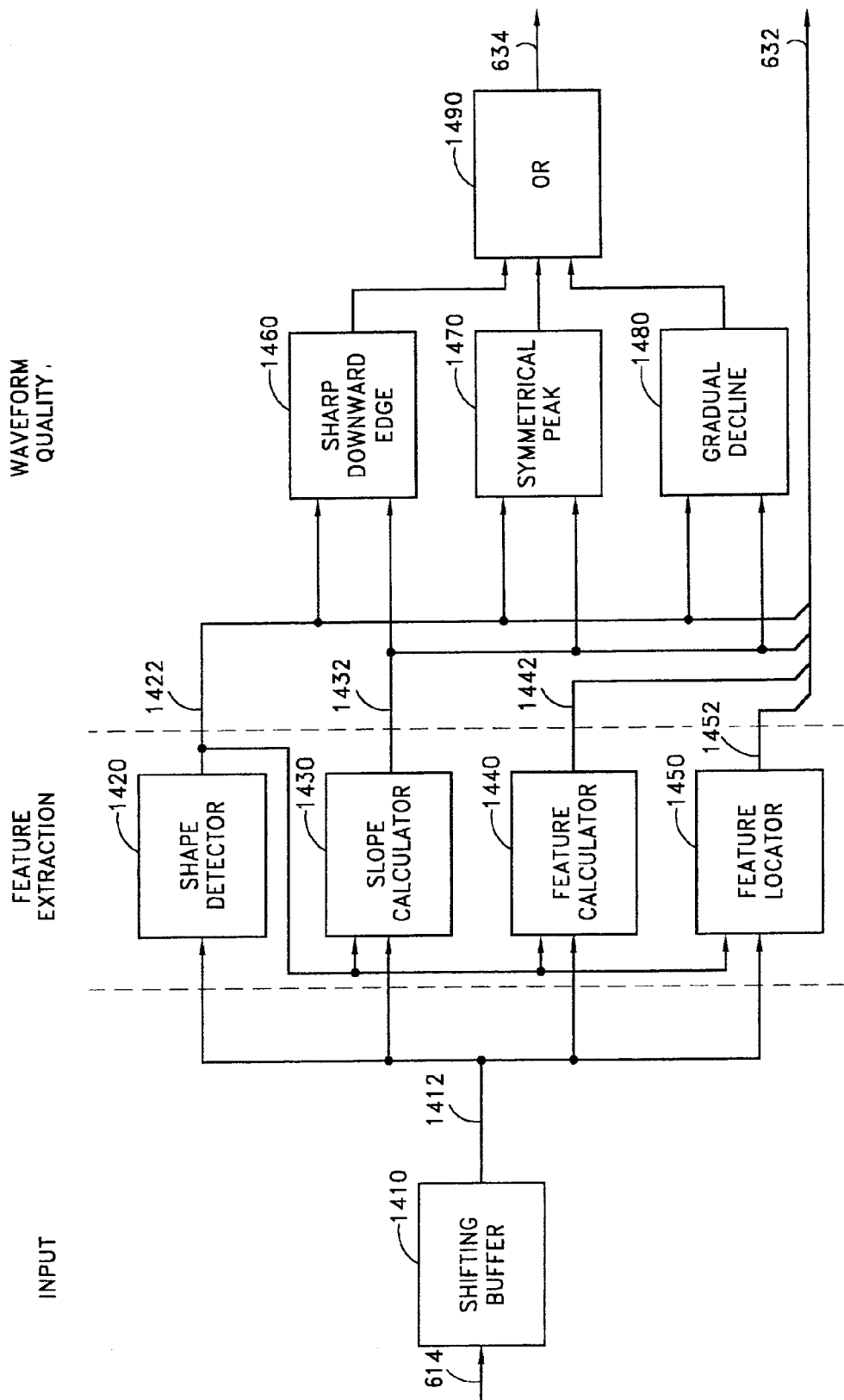


FIG. 14

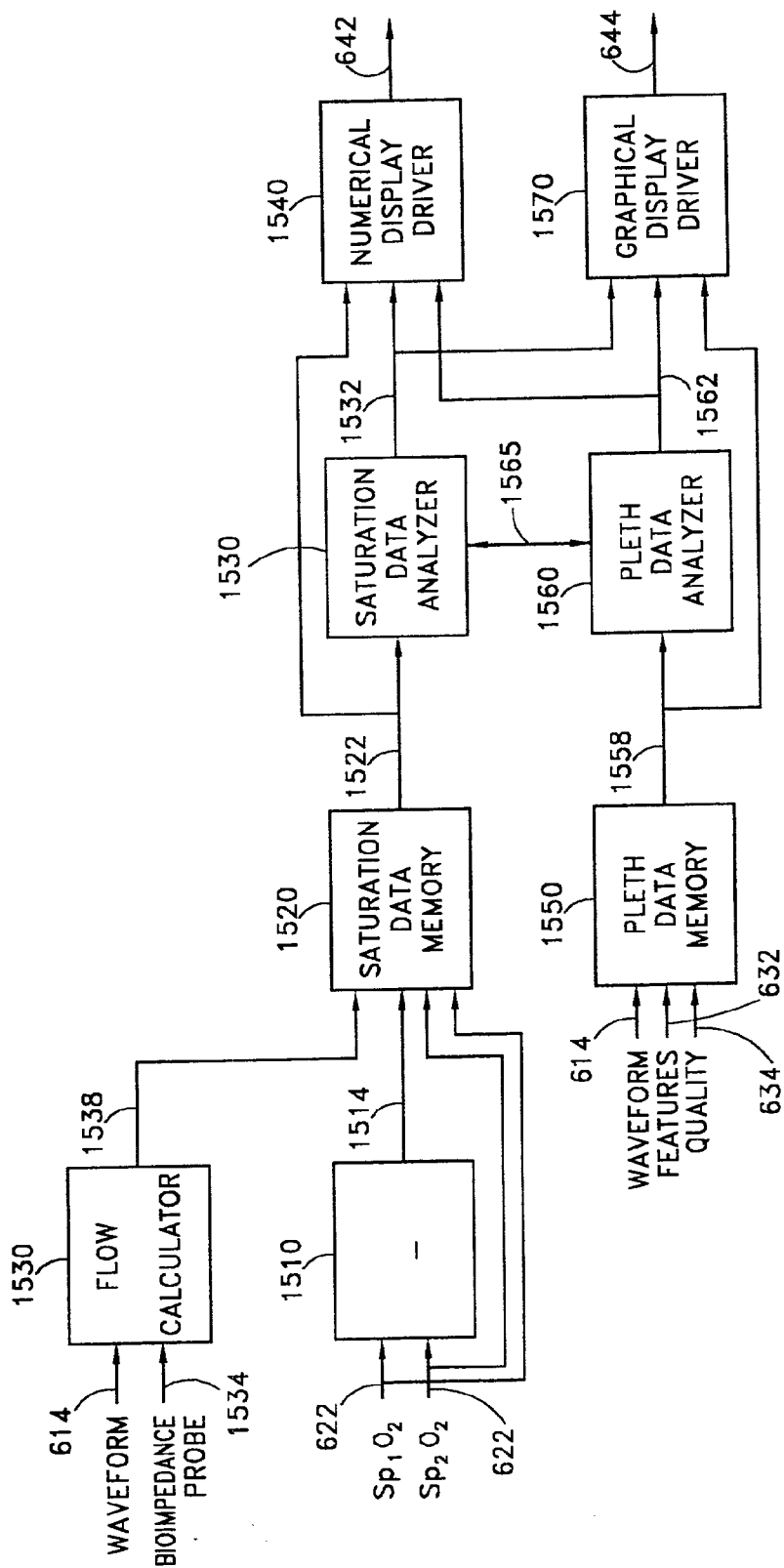


FIG. 15

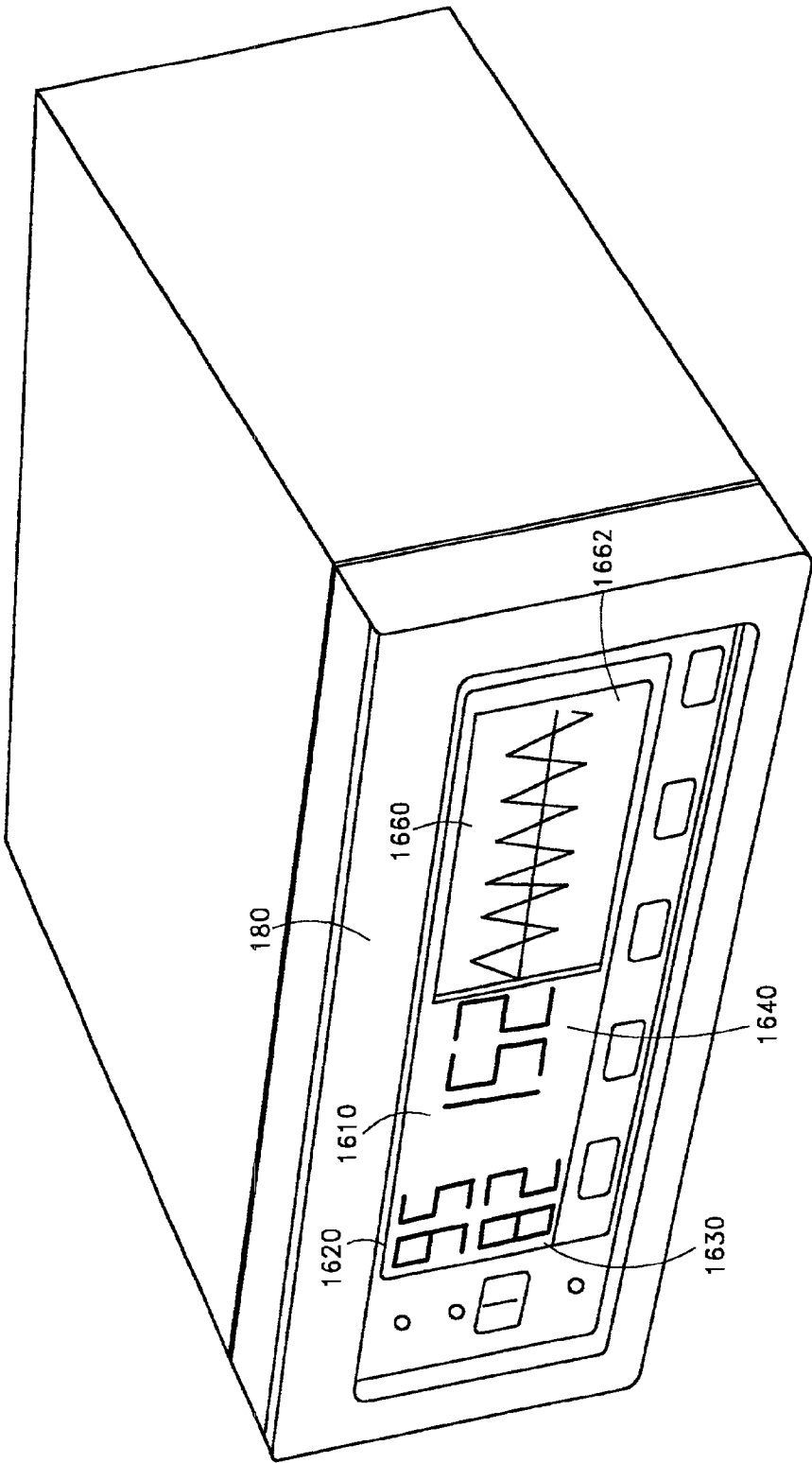


FIG. 16A

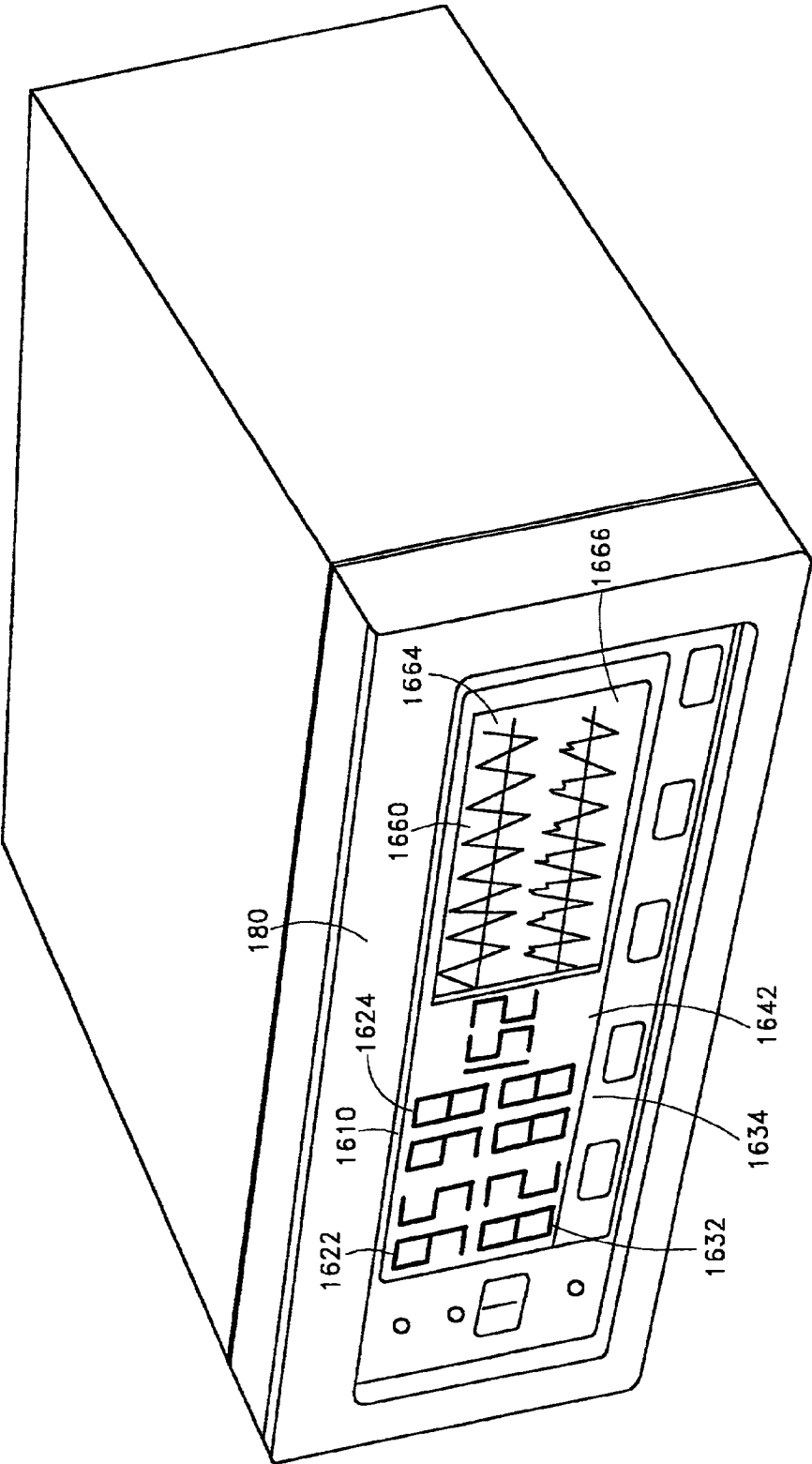


FIG. 16B

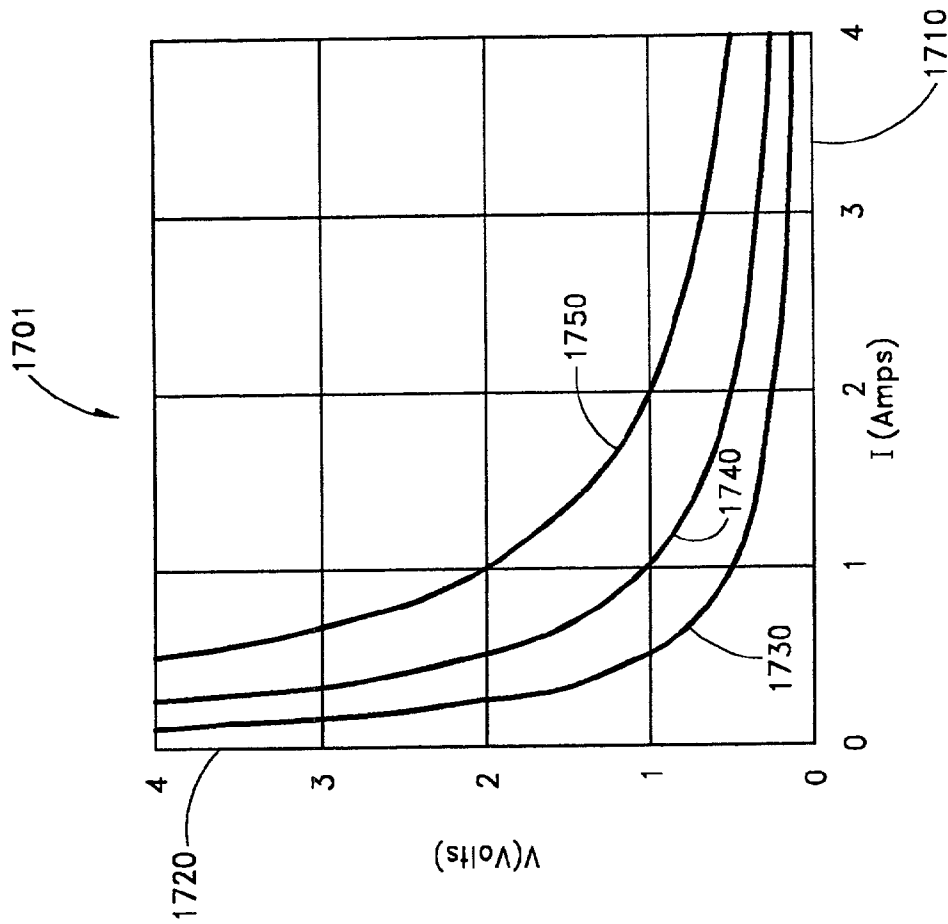


FIG. 17A

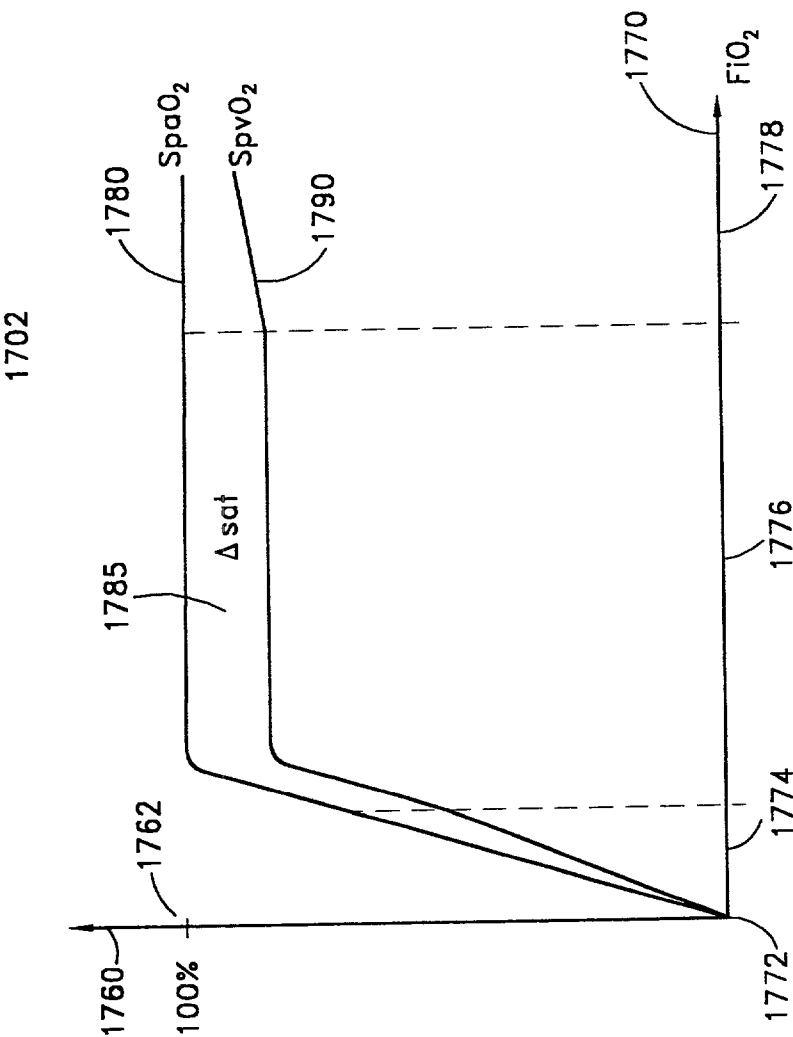


FIG. 17B

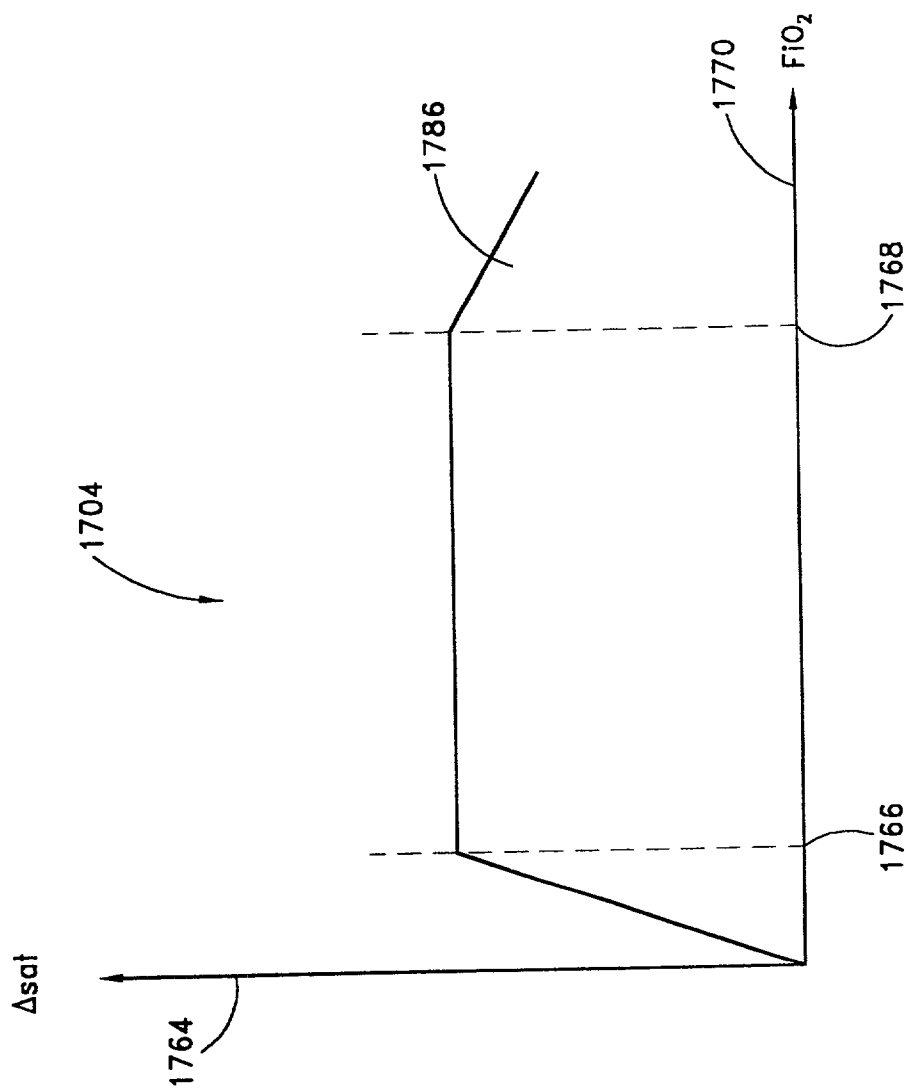


FIG. 17C

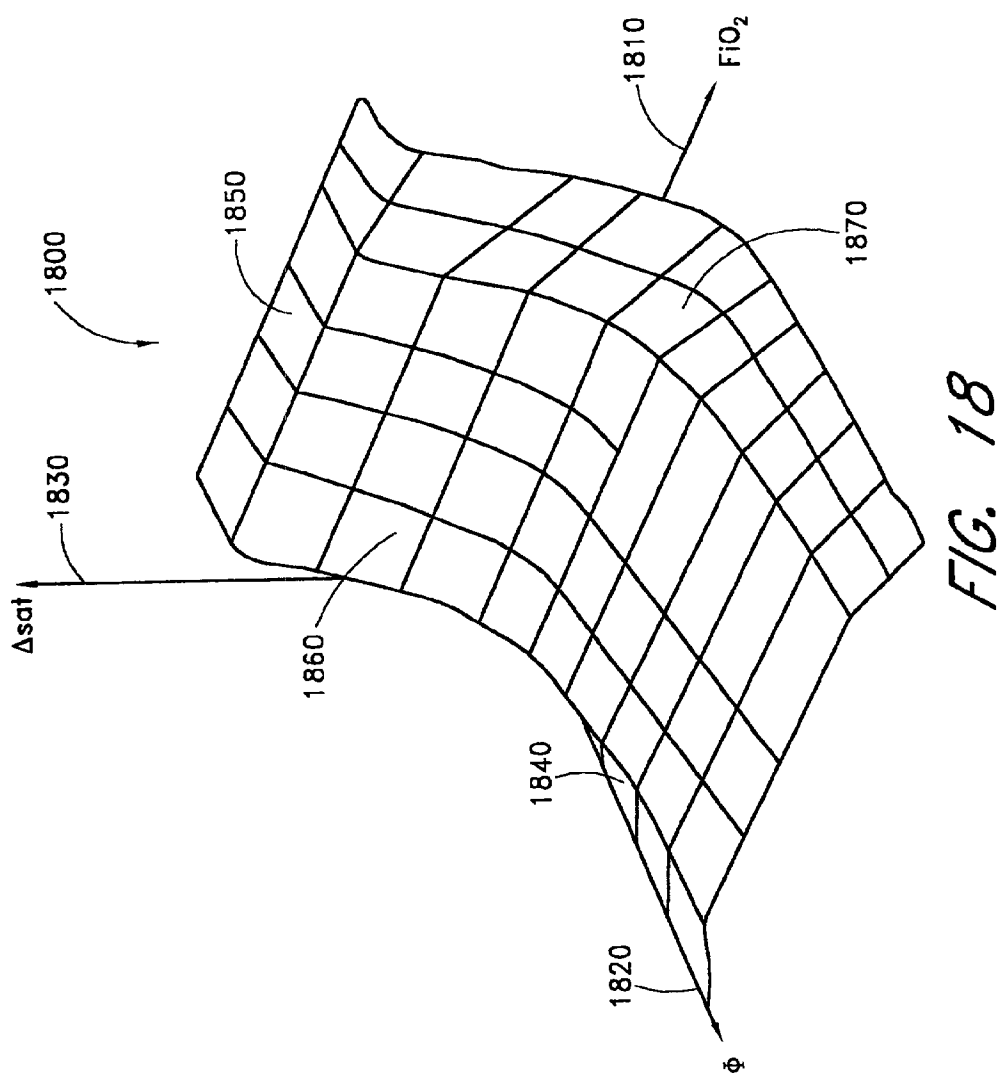


FIG. 18

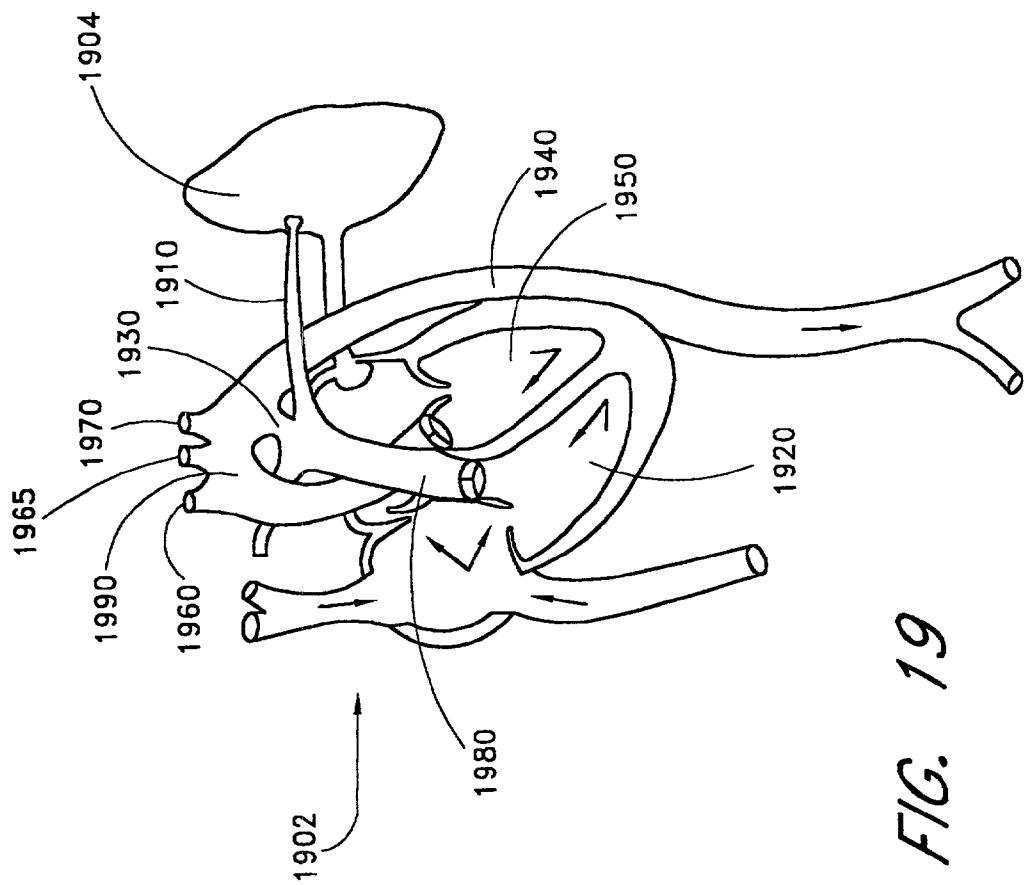
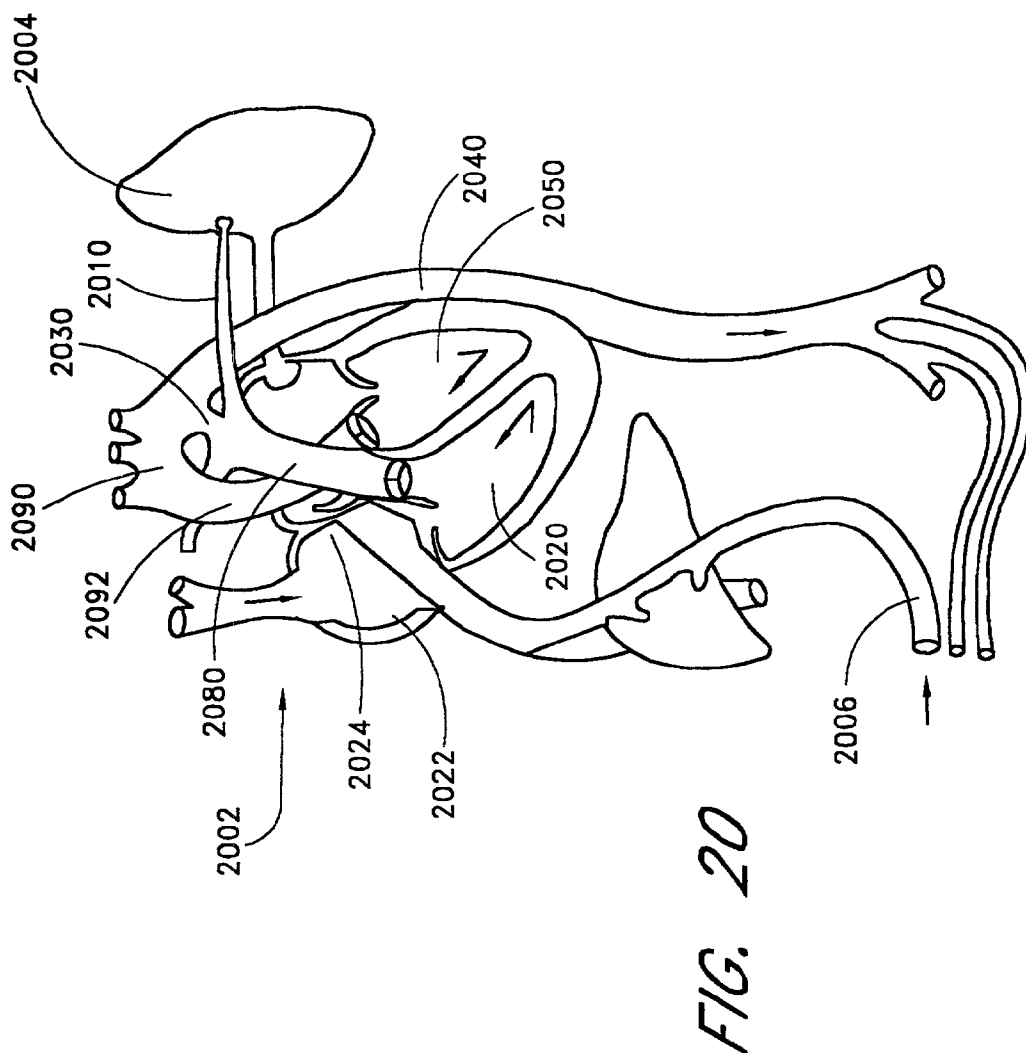


FIG. 19



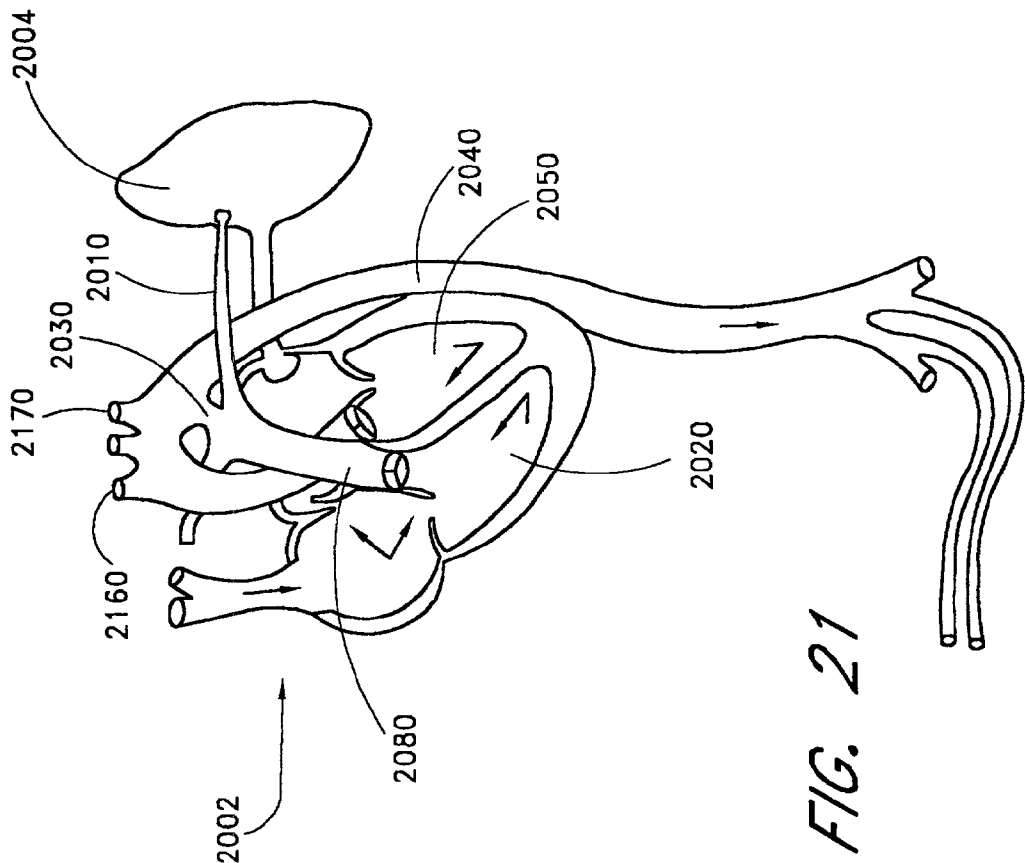


FIG. 21

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STEREO PULSE OXIMETER**BACKGROUND OF THE INVENTION**

[0001] The measurement of oxygen delivery to the body and the corresponding oxygen consumption by its organs and tissues is vitally important to medical practitioners in the diagnosis and treatment of various medical conditions. Oxygen delivery, the transport of oxygen from the environment to organs and tissues, depends on the orchestration of several interrelated physiologic systems. Oxygen uptake is determined by the amount of oxygen entering the lung and the adequacy of gas exchange within the lung. This gas exchange is determined by the diffusion of oxygen from the alveolar space to the blood of the pulmonary capillaries. Oxygen is subsequently transported to all organs and tissues by blood circulation maintained by the action of the heart. The availability of oxygen to the organs and tissues is determined both by cardiac output and by the oxygen content in the blood. Oxygen content, in turn, is affected by the concentration of available hemoglobin and hemoglobin oxygen saturation. Oxygen consumption is related to oxygen delivery according to Fick's axiom, which states that oxygen consumption in the peripheral tissues is equal to oxygen delivery via the airway.

[0002] Oxygen delivery and oxygen consumption can be estimated from a number of measurable parameters. Because of the diagnostic impracticalities of measuring oxygen uptake and cardiac output, oxygen delivery is typically assessed from the oxygen status of arterial blood alone, such as arterial oxygen partial pressure, P_aO_2 , and arterial oxygen saturation, S_aO_2 . P_aO_2 represents the relatively small amount of oxygen dissolved in the blood plasma. S_aO_2 represents the much larger amount of oxygen chemically bound to the blood hemoglobin. Oxygen consumption is typically assessed from the oxygen status of mixed venous blood, i.e. the oxygen saturation of blood from the pulmonary artery, S_vO_2 , which is used to estimate the O_2 concentration of blood returning from all tissues and organs of the body. These parameters can be measured by both invasive and non-invasive techniques, except S_vO_2 , which requires an invasive measurement.

[0003] Invasive techniques include blood gas analysis using the in vitro measurement of extracted arterial or venous blood, drawn with a syringe and needle or an intervascular catheter. Arterial blood is commonly obtained by puncturing the brachial, radial or femoral artery. Venous blood can be obtained from an arm vein, but such a sample reflects only local conditions. To obtain mixed venous blood, which represents the composite of all venous blood, a long catheter is typically passed through the right heart and into the main pulmonary artery from a peripheral vein. Extracted blood gas analysis utilizes blood gas machines or oximeters. A blood gas machine measures the partial pressure of oxygen, PO_2 , using a "Clark electrode" that detects the current generated by oxygen diffusing to a sealed platinum electrode across a gas permeable membrane. An oximeter measures the oxygen saturation, SO_2 , of oxygenated and deoxygenated hemoglobin using spectrophotometry techniques that detect the differential absorption of particular wavelengths of light by these blood components.

[0004] Invasive monitoring also includes the in vivo monitoring of blood gas via a catheter sensor inserted into an

artery or vein. Miniaturization of the Clark electrode allows placement of the electrode in a catheter for continuous measurement of PO_2 . A fiber optic equipped catheter attached to an external oximeter allows continuous measurement of oxygen saturation. Because of risks inherent in catheterization and the promotion of blood coagulation by certain sensors, these techniques are typically only used when vitally indicated.

[0005] Non-invasive techniques include pulse oximetry, which allows the continuous in vivo measurement of arterial oxygen saturation and pulse rate in conjunction with the generation of a photoplethysmograph waveform. Measurements rely on sensors which are typically placed on the fingertip of an adult or the foot of an infant. Non-invasive techniques also include transcutaneous monitoring of PO_2 , accomplished with the placement of a heated Clark electrode against the skin surface. These non-invasive oxygen status measurement techniques are described in further detail below.

SUMMARY OF THE INVENTION

[0006] Prior art invasive oxygen assessment techniques are inherently limited. Specifically, in vitro measurements, that is, blood extraction and subsequent analysis in a blood gas machine or an oximeter, are non-simultaneous and non-continuous. Further, in vivo measurements through catheterization are not casual procedures and are to be particularly avoided with respect to neonates. Prior art noninvasive techniques are also limited. In particular, conventional pulse oximeters are restricted to measurement of arterial oxygen saturation at a single patient site. Also, transcutaneous monitoring is similarly restricted to the measurement of an estimate of arterial partial pressure at a single patient site, among other limitations discussed further below.

[0007] The stereo pulse oximeter according to the present invention overcomes many of the limitations of prior art oxygen status measurements. The word "stereo" comes from the Greek word stereos, which means "solid" or three-dimensional. For example, stereophonic systems use two or more channels to more accurately reproduce sound. The stereo pulse oximeter is similarly multi-dimensional, providing simultaneous, continuous, multiple-site and multiple-parameter oxygen status and plethysmograph (photoplethysmograph) measurements. The stereo pulse oximeter provides a benefit in terms of cost and patient comfort and safety over invasive oxygen status estimation techniques. The multi-dimensional aspects of this invention further provide oxygen status and plethysmograph measurements not available from current noninvasive techniques. In addition, the stereo pulse oximeter allows the isolation of noise artifacts, providing more accurate oxygen status and plethysmograph measurements than available from conventional techniques. The result is improved patient outcome based on a more accurate patient assessment and better management of patient care.

[0008] In one aspect of the stereo pulse oximeter, data from a single sensor is processed to advantageously provide continuous and simultaneous multiple-parameter oxygen status and plethysmograph measurements from a particular tissue site. This is in contrast to a conventional pulse oximeter that provides only arterial oxygen saturation data from a tissue site. In particular a physiological monitor

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comprises a sensor interface and a signal processor. The sensor interface is in communication with a peripheral tissue site and has an output responsive to light transmitted through the site. The signal processor is in communication with the sensor interface output and provides a plurality of parameters corresponding to the oxygen status of the site, the plethysmograph features of the site or both. The parameters comprise a first value and a second value related to the peripheral tissue site. In one embodiment, the first value is an arterial oxygen saturation and the second value is a venous oxygen saturation. In this embodiment, another parameter provided may be the difference between arterial oxygen saturation and venous oxygen saturation at the tissue site. The venous oxygen saturation is derived from an active pulse generated at the site. The signal processor output may further comprise a scattering indicator corresponding to the site, and the sensor interface may further comprise a pulser drive, which is responsive to the scattering indicator to control the amplitude of the active pulse. One of the parameter values may also be an indication of perfusion.

[0009] In another aspect of the stereo pulse oximeter, data from multiple sensors is processed to advantageously provide continuous and simultaneous oxygen status measurements from several patient tissue sites. This is in contrast to a conventional pulse oximeter that processes data from a single sensor to provide oxygen status at a single tissue site. In particular, a physiological monitor comprises a plurality of sensor interfaces each in communications with one of a plurality of peripheral tissue sites. Each of the sensor interfaces has one of a plurality of outputs responsive to light transmitted through a corresponding one of the tissue sites. A signal processor is in communication with the sensor interface outputs and has a processor output comprising a plurality of parameters corresponding to the oxygen status of the sites, the plethysmograph features of the sites or both. The parameters may comprise a first value relating to a first of the peripheral tissue sites and a second value relating to a second of the peripheral tissue sites. In one embodiment, the first value and the second value are arterial oxygen saturations. In another embodiment, the first value and the second value are plethysmograph waveform phases. The physiological monitor may further comprise a sensor attachable to each of the tissue sites. This sensor comprises a plurality of emitters and a plurality of detectors, where at least one of the emitters and at least one of the detectors is associated with each of the tissue sites. The sensor also comprises a connector in communications with the sensor interfaces. A plurality of signal paths are attached between the emitters and the detectors at one end of the sensor and the connector at the other end of the sensor.

[0010] In yet another aspect of the stereo pulse oximeter, data from multiple sensors is processed to advantageously provide a continuous and simultaneous comparison of the oxygen status between several tissue sites. A conventional oximeter, limited to measurements at a single tissue site, cannot provide these cross-site comparisons. In particular a physiological monitoring method comprises the steps of deriving a reference parameter and a test parameter from oxygen status measured from at least one of a plurality of peripheral tissue sites and comparing that reference parameter to the test parameter so as to determine a patient condition. The reference parameter may be a first oxygen saturation value and the test parameter a second oxygen saturation value. In that case, the comparing step computes

a delta oxygen saturation value equal to the arithmetic difference between the first oxygen saturation value and the second oxygen saturation value. In one embodiment, the reference parameter is an arterial oxygen saturation measured at a particular one the tissue sites and the test parameter is a venous oxygen saturation measured at that particular site. In another embodiment, the reference parameter is a first arterial oxygen saturation value at a first of the tissue sites, the test parameter is a second arterial oxygen saturation value at a second of the tissue sites. In yet another embodiment, the reference parameter is a plethysmograph feature measured at a first of the sites, the test parameter is a plethysmograph feature measured at a second of the sites and the monitoring method comparison step determines the phase difference between plethysmographs at the first site and the second site. In a further embodiment, the comparing step determines a relative amount of damping between plethysmographs at the first site and the second site. The multi-dimensional features of these embodiments of the stereo pulse oximeter can be advantageously applied to the diagnosis and managed medical treatment of various medical conditions. Particularly advantageous applications of stereo pulse oximetry include oxygen titration during oxygen therapy, nitric oxide titration during therapy for persistent pulmonary hypertension in neonates (PPHN), detection of a patent ductus arteriosus (PDA), and detection of an aortic coarctation.

BRIEF DESCRIPTION OF THE DRAWINGS

[0011] The present invention will be described in detail below in connection with the following drawing figures in which:

[0012] **FIG. 1A** is a top-level block diagram of a stereo pulse oximeter according to the present invention;

[0013] **FIG. 1B** shows a single-sensor alternative embodiment to **FIG. 1A**;

[0014] **FIG. 2** is a block diagram of the stereo pulse oximeter sensor interface;

[0015] **FIG. 3** is a graph illustrating the absorption of red and infrared wavelengths by both oxygenated and deoxygenated hemoglobin;

[0016] **FIG. 4** is a graph showing the empirical relationship between the "red over infrared" ratio and arterial oxygen saturation;

[0017] **FIG. 5** is a block diagram of the analog signal conditioning for the sensor interface;

[0018] **FIG. 6** is a functional block diagram of the stereo pulse oximeter signal processing;

[0019] **FIG. 7** is a functional block diagram of the front-end signal processing;

[0020] **FIG. 8** is a graph depicting the frequency spectrum of an arterial intensity signal;

[0021] **FIG. 9** is a graph depicting the frequency spectrum of a combined arterial and venous intensity signal;

[0022] **FIG. 10** is a functional block diagram of the saturation calculation signal processing;

[0023] **FIG. 11** is a graph illustrating a plethysmograph waveform;

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[0024] FIG. 12 is a graph illustrating the absorption contribution of various blood and tissue components;

[0025] FIG. 13 is a graph illustrating an intensity "plethysmograph" pulse oximetry waveform;

[0026] FIG. 14 is a functional block diagram of the plethysmograph feature extraction signal processing;

[0027] FIG. 15 is a functional block diagram of the multiple parameter signal processing;

[0028] FIG. 6A is an illustration of a single-site stereo pulse oximeter display screen;

[0029] FIG. 16B is an illustration of a multi-site stereo pulse oximeter display screen;

[0030] FIG. 17A is a graph depicting a family of constant power curves for the electrical analog of constant oxygen consumption;

[0031] FIG. 17B is a graph depicting arterial and venous oxygen saturation versus fractional inspired oxygen;

[0032] FIG. 17C is a graph depicting arterial minus venous oxygen saturation versus fractional inspired oxygen;

[0033] FIG. 18 is a three-dimensional graph depicting a delta oxygen saturation surface;

[0034] FIG. 19 is an illustration of a neonatal heart depicting a pulmonary hypertension condition;

[0035] FIG. 20 is an illustration of a fetal heart depicting the ductus arteriosus; and

[0036] FIG. 21 is an illustration of a neonatal heart depicting a patent ductus arteriosus (PDA).

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0037] Stereo Pulse Oximetry

[0038] FIG. 1A illustrates the multi-dimensional features of a stereo pulse oximeter 100 according to the present invention. Shown in FIG. 1A is an exemplary stereo pulse oximeter configuration in which a first sensor 110 is attached to a neonate's left hand, a second sensor 120 is attached to one of the neonate's feet, and a third sensor 130 is attached to the neonate's right hand. In general, these sensors are used to obtain oxygen status and photoplethysmograph measurements at peripheral sites, including a person's ears and face, such as the nose and regions of the mouth in addition to hands, feet and limbs, but not including internal sites such as internal organs and the brain. Each sensor 110, 120, 130 provides a stream of data through a corresponding sensor interface 114, 124, 134 to the digital signal processor (DSP) 150. For example, the first sensor 110 is connected to an input 112 of the first sensor interface 114, and the output 118 of the first sensor interface 114 is attached to a first data channel input 152 of the DSP 150. Similarly, the second sensor 120 provides data to a second data channel input 154 and the third sensor 130 provides data to a third data channel input 158.

[0039] FIG. 1B illustrates an alternative embodiment of the separate sensors 110, 120, 130 (FIG. 1A). A stereo sensor 140 has multiple branches 112, 122, 132 each terminating in a sensor portion 114, 124, 134. Each sensor portion 114, 124, 134 has two light emitters and a light detector, as

described below, and is attachable to a separate patient site. Thus, the stereo sensor 140 advantageously provides a single sensor device having multiple light emitters and multiple light detectors for attachment to multiple patient tissue sites. A combination of the stereo sensor 140 and a single patient cable 142 advantageously allows a single connection 144 at the stereo pulse oximeter 100 and a single connection 146 at the stereo sensor 140.

[0040] The DSP 150 can independently process each data channel input 152, 154, 158 and provide outputs 162 typical of pulse oximetry outputs, such as arterial oxygen saturation, Sp_aO_2 , the associated plethysmograph waveform and the derived pulse rate. In contrast with a conventional pulse oximeter, however, these outputs 162 include simultaneous measurements at each of several patient tissue sites. That is, for the configuration of FIG. 1A, the stereo pulse oximeter 100 simultaneously displays Sp_aO_2 and an associated plethysmograph waveform for three tissue sites in addition to the patient's pulse rate obtained from any one of sites. Further, the DSP 150 can provide unique outputs unavailable from conventional pulse oximeters. These outputs 164 include venous oxygen saturation, Sp_vO_2 , a comparison of arterial and venous oxygen saturation, $\Delta sat = Sp_{av}O_2 = Sp_aO_2 - Sp_vO_2$, and pleth, which denotes plethysmograph shape parameters, for each site. In addition, the DSP 150 can provide cross-site outputs that are only available using stereo pulse oximetry. These unique cross-site outputs 168 include $\Delta sat_{xy} = Sp_{ax}O_2 - Sp_{ay}O_2$, which denotes the arterial oxygen saturation at site x minus the arterial oxygen saturation at site y. Also included in these outputs 168 is $\Delta pleth_{xy}$, which denotes a comparison of plethysmograph shape parameters measured at site x and site y, as described in detail below. The stereo pulse oximeter also includes a display 180 capable of showing the practitioner the oxygen status and plethysmograph parameters described above. The display 180 has a multiple channel graphical and numerical display capability as described in more detail below.

[0041] Pulse Oximetry Sensor

[0042] FIG. 2 depicts one stereo pulse oximeter data channel having a sensor 110 and a sensor interface 114 providing a single data channel input 152 to the DSP 150. The sensor 110 is used to measure the intensity of red and infrared light after transmission through a portion of the body where blood flows close to the surface, such as a fingertip 202. The sensor 110 has two light emitters, each of which may be, for example, a light-emitting diode (LED). A red emitter 212, which transmits light centered at a red wavelength and an infrared (IR) emitter 214, which transmits light centered at an infrared wavelength are placed adjacent to, and illuminate, a tissue site. A detector 218, which may be a photodiode, is used to detect the intensity of the emitted light after it passes through, and is partially absorbed by, the tissue site. The emitters 212, 214 and detector 218 are secured to the tissue site, with the emitters 212, 214 typically spaced on opposite sides of the tissue site from the detector 218.

[0043] To distinguish between tissue absorption at the two wavelengths, the red emitter 212 and infrared emitter 214 are modulated so that only one is emitting light at a given time. In one embodiment, the red emitter 212 is activated for a first quarter cycle and is off for the remaining three-quarters cycle; the infrared emitter 214 is activated for a

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third quarter cycle and is off for the remaining three-quarters cycle. That is, the emitters **212**, **214** are cycled on and off alternately, in sequence, with each only active for a quarter cycle and with a quarter cycle separating the active times. The detector **218** produces an electrical signal corresponding to the red and infrared light energy attenuated from transmission through the patient tissue site **202**. Because only a single detector **218** is used, it receives both the red and infrared signals to form a time-division-multiplexed (TDM) signal. This TDM signal is coupled to the input **112** of the sensor interface **114**. One of ordinary skill in the art will appreciate alternative activation sequences for the red emitter **212** and infrared emitter **214** within the scope of this invention, each of which provides a time multiplexed signal from the detector **218** allowing separation of red and infrared signals and determination and removal of ambient light levels in downstream signal processing.

[0044] To compute Sp_aO_2 , pulse oximetry relies on the differential light absorption of oxygenated hemoglobin, HbO_2 , and deoxygenated hemoglobin, Hb , to compute their respective concentrations in the arterial blood. This differential absorption is measured at the red and infrared wavelengths of the sensor **110**. The relationship between arterial oxygen saturation and hemoglobin concentration can be expressed as:

$$Sp_aO_2 = 100 C_{HbO_2} / (C_{Hb} + C_{HbO_2}) \quad (1)$$

[0045] That is, arterial oxygen saturation is the percentage concentration of oxygenated hemoglobin compared to the total concentration of oxygenated hemoglobin and deoxygenated hemoglobin in the arterial blood. Sp_aO_2 is actually a measure of the partial oxygen saturation of the hemoglobin because other hemoglobin derivatives, such as COHb and MetHb, are not taken into consideration.

[0046] FIG. 3 shows a graph **300** of the optical absorption properties of HbO_2 and Hb . The graph **300** has an x-axis **310** corresponding to wavelength and a y-axis **320** corresponding to hemoglobin absorption. An Hb curve **330** shows the light absorption properties of deoxygenated hemoglobin. An HbO_2 curve **340** shows the light absorption properties of oxygenated hemoglobin. Pulse oximetry measurements are advantageously made at a red wavelength **350** corresponding to 660 nm and an infrared wavelength **360** corresponding to 905 nm. This graph **300** shows that, at these wavelengths **350**, **360**, deoxygenated hemoglobin absorbs more red light than oxygenated hemoglobin, and, conversely, oxygenated hemoglobin absorbs more infrared light than deoxygenated hemoglobin.

[0047] In addition to the differential absorption of hemoglobin derivatives, pulse oximetry relies on the pulsatile nature of arterial blood to differentiate hemoglobin absorption from absorption of other constituents in the surrounding tissues. Light absorption between systole and diastole varies due to the blood volume change from the inflow and outflow of arterial blood at a peripheral tissue site. This tissue site might also comprise skin, muscle, bone, venous blood, fat, pigment, etc., each of which absorbs light. It is assumed that the background absorption due to these surrounding tissues is invariant and can be ignored. Thus, blood oxygen saturation measurements are based upon a ratio of the time-varying or AC portion of the detected red and infrared signals with respect to the time-invariant or DC portion. This AC/DC ratio normalizes the signals and accounts for varia-

tions in light pathlengths through the measured tissue. Further, a ratio of the normalized absorption at the red wavelength over the normalized absorption at the infrared wavelength is computed:

$$RD/IR = (Red_{AC}/Red_{DC}) / (IR_{AC}/IR_{DC}) \quad (2)$$

[0048] where Red_{AC} and IR_{AC} are the root-mean-square (RMS) of the corresponding time-varying signals. This "red-over-infrared, ratio-of-ratios" cancels the pulsatile signal. The desired Sp_aO_2 measurement is then computed from this ratio.

[0049] FIG. 4 shows a graph **400** depicting the relationship between RD/IR and Sp_aO_2 . This relationship can be approximated from Beer-Lambert's Law, as outlined below. However, it is most accurately determined by statistical regression of experimental measurements obtained from human volunteers and calibrated measurements of oxygen saturation. The result can be depicted as a curve **410**, with measured values of RD/IR shown on a y-axis **420** and corresponding saturation values shown on an x-axis **430**. In a pulse oximeter device, this empirical relationship can be stored in a read-only memory (ROM) look-up table so that Sp_aO_2 can be directly read-out from input RD/IR measurements.

[0050] According to the Beer-Lambert law of absorption, the intensity of light transmitted through an absorbing medium is given by:

$$I = I_0 \exp(-\sum_{i=1}^N \epsilon_{i,\lambda} c_i x_i) \quad (3)$$

[0051] where I_0 is the intensity of the incident light, $\epsilon_{i,\lambda}$ is the absorption coefficient of the i^{th} constituent at a particular wavelength λ , c_i is the concentration coefficient of the i^{th} constituent and x_i is the optical path length of the i^{th} constituent. As stated above, assuming the absorption contribution by all constituents but the arterial blood is constant, taking the natural logarithm of both sides of equation (3) and removing time invariant terms yields:

$$\ln(I) = -[\epsilon_{HbO_2,\lambda} C_{HbO_2} + \epsilon_{Hb,\lambda} C_{Hb}] x(t) \quad (4)$$

[0052] Measurements taken at both red and infrared wavelengths yield:

$$RD(t) = -[\epsilon_{HbO_2, RD} C_{HbO_2} + \epsilon_{Hb, RD} C_{Hb}] x_{RD}(t) \quad (5)$$

$$IR(t) = -[\epsilon_{HbO_2, IR} C_{HbO_2} + \epsilon_{Hb, IR} C_{Hb}] x_{IR}(t) \quad (6)$$

[0053] Taking the ratio $RD(t)/IR(t)$ and assuming $x_{RD}(t) \approx x_{IR}(t)$ yields:

$$RD/IR = [\epsilon_{HbO_2, RD} C_{HbO_2} + \epsilon_{Hb, RD} C_{Hb}] / [\epsilon_{HbO_2, IR} C_{HbO_2} + \epsilon_{Hb, IR} C_{Hb}] \quad (7)$$

[0054] Assuming further that:

$$C_{HbO_2} + C_{Hb} = 1 \quad (8)$$

[0055] then equation (1) can be solved in terms of RD/IR yielding a curve similar to the graph **400** of FIG. 4.

[0056] Sensor Interface

[0057] FIG. 2 also depicts the sensor interface **114** for one data channel. An interface input **112** from the sensor **110** is coupled to an analog signal conditioner **220**. The analog signal conditioner **220** has an output **223** coupled to an analog-to-digital converter (ADC) **230**. The ADC output **118** is coupled to the DSP **150**. The analog signal conditioner also has a gain control input **225** from the DSP **150**. The functions of the analog signal conditioner **220** are explained in detail below. The ADC **230** functions to digitize the input

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signal **112** prior to further processing by the DSP **150**, as described below. The sensor interface **114** also has an emitter current control input **241** coupled to a digital-to-analog converter (DAC) **240**. The DSP provides control information to the DAC **240** via the control input **241** for a pair of emitter current drivers **250**. One driver output **252** couples to the red emitter **212** of the sensor **110**, and another driver output **254** couples to the IR emitter **214** of the sensor **110**.

[0058] FIG. 5 illustrates one embodiment of the analog signal conditioner **220**. The analog signal conditioner **220** receives a composite intensity signal **112** from the sensor detector **218** (FIG. 2) and then filters and conditions this signal prior to digitization. The embodiment shown has a preamplifier **510**, a high pass filter **520**, a programmable gain amplifier **530** and a low pass filter **540**. The low pass filter output **223** is coupled to the ADC **230** (FIG. 2). The preamplifier **510** converts the current signal **112** from the detector **218** (FIG. 2) to a corresponding amplified voltage signal. The gain in the preamplifier **510** is selected in order to prevent ambient light in the signal **112** from saturating the preamplifier **510** under normal operating conditions. The preamplifier output **512** is coupled to the high pass filter **520**, which removes the DC component of the detector signal **112**. The corner frequency of the high pass filter **520** is set well below the multiplexing frequency of the red and infrared emitters **212**, **214** (FIG. 2). The high pass filter output **522** couples to the programmable gain amplifier **530**, which also accepts a programming input **225** from the DSP **150** (FIG. 2). This gain is set at initialization or at sensor placement to compensate for variations from patient to patient. The programmable gain amplifier output **532** couples to a low-pass filter **540** to provide anti-aliasing prior to digitization.

[0059] As described above, pulse oximetry measurements rely on the existence of a pulsatile signal. The natural heart beat provides a pulsatile signal that allows measurement of arterial oxygen saturation. In the systemic circulation, all arterial pulsations are damped before flow enters the capillaries, and none are transmitted into the veins. Thus, there is no arterial pulse component in the venous blood and absorption caused by venous blood is assumed canceled by the ratio-of-ratio operation described above. Venous blood, being at a relatively low pressure, will “slosh back and forth” during routine patient motions, such as shivering, waving and tapping. This venous blood sloshing creates a time-varying signal that is considered “noise” and can easily overwhelm conventional ratio-based pulse oximeters. Advanced pulse oximetry techniques allow measurement of Sp_vO_2 under these circumstances. For example, such advanced techniques are disclosed in U.S. Pat. No. 5,632, 272, which is assigned to the assignee of the current application. This measurement is only available during motion or other physiological events causing a time-varying venous signal.

[0060] The venous blood may also have a pulsatile component at the respiration rate, which can be naturally induced or ventilator induced. In adults, the natural respiration rate is 10-15 beats per minute (bpm). In neonates, this natural respiration rate is 30-60 bpm. The ventilator induced pulse rate depends on the ventilator frequency. If this respiration

induced venous pulse is of sufficient magnitude, advanced pulse oximetry techniques, described below, allow measurement of Sp_vO_2 .

[0061] A controlled physiological event, however, can be created that allows for a continuous measurement of venous oxygen saturation, independent of motion or respiration. U.S. Pat. No. 5,638,816, which is assigned to the assignee of the current application discloses a technique for inducing an intentional active perturbation of the blood volume of a patient, and is referred to as an “active pulse.” Because peripheral venous oxygen saturation, Sp_vO_2 , is a desirable parameter for stereo pulse oximetry applications, it is advantageous to provide for a continuous and controlled pulsatile venous signal.

[0062] FIG. 2 depicts an active pulse mechanism used in conjunction with a pulse oximetry sensor. An active pulser **260** physically squeezes or otherwise perturbs a portion of patient tissue **270** in order to periodically induce a “pulse” in the blood at the tissue site **202**. A pulser drive **280** generates a periodic electrical signal to a transducer **262** attached to the patient. The transducer **262** creates a mechanical force against the patient tissue **270**. For example, the pulser **260** could be a solenoid type device with a plunger that presses against the fleshy tissue to which it is attached. The DSP **150** provides pulse drive control information to a digital to analog converter (DAC) **290** via the control input **291**. The DAC output **292** is coupled to the pulser drive **280**. This allows the processor to advantageously control the magnitude of the induced pulse, which moderates scattering as described below. The pulser **260** could be a pressure device as described above. Other pressure mechanisms, for example a pressure cuff, could be similarly utilized. Other methods, such as temperature fluctuations or other physiological changes, which physiologically alter a fleshy medium of the body on a periodic basis to modulate blood volume at a nearby tissue site could also be used. Regardless of the active pulse mechanism, this modulated blood volume is radiated by a pulse oximeter sensor and the resulting signal is processed by the signal processing apparatus described below to yield Sp_vO_2 .

[0063] Signal Processor

[0064] FIG. 6 illustrates the processing functions of the digital signal processor (DSP) **150** (FIG. 1A). Each data channel input **152**, **154**, **158** (FIG. 1A) is operated on by one or more of the front-end processor **610**, saturation calculator **620**, plethysmograph feature extractor **630** and multiple parameter processor **640** functions of the DSP **150**. First, a digitized signal output from the ADC **230** (FIG. 2) is input **602** to the front-end processor **610**, which demultiplexes, filters, normalizes and frequency transforms the signal, as described further below. A front-end output **612** provides a red signal spectrum and an IR signal spectrum for each data channel as inputs to the saturation calculator **620**. Another front-end output **614** provides a demultiplexed, normalized IR plethysmograph for each data channel as an input to the feature extractor **630**. The saturation calculator output **622** provides arterial and venous saturation data for each data channel as input to the multiple parameter processor **640**. One feature extractor output **632** provides data on various plethysmograph shape parameters for each data channel as input into the multiple parameter processor **640**. Another feature extractor output **634**, also coupled to multiple param-

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eter processor 640, provides an indication of plethysmograph quality and acts as a threshold for determining whether to ignore portions of the input signal 602. The multiple parameter processor has a numerical output 642 that provides same-channel Δsat parameters and cross-channel parameters, such as Δsat_{xy} or Δpleth_{xy} to a display 180 (FIG. 1A). The numeric output 642 may also provide saturation and plethysmograph parameters directly from the saturation calculator 620 or the feature extractor 630 without further processing other than data buffering. The multiple parameter processor also has a graphical output 644 that provides plethysmograph waveforms for each data channel in addition to graphics, depending on a particular application, the indicate the trend of the numerical parameters described above.

[0065] Front-end Processor

[0066] FIG. 7 is a functional block diagram of the front-end processor 610 for the stereo pulse oximeter. The digitized sensor output 118 (FIG. 2) is an input signal 602 to a demultiplexer 710, which separates the input signal 602 into a red signal 712 and an infrared signal 714. The separated red and infrared signals 712, 714 are each input to a filter 720 to remove unwanted artifacts introduced by the demultiplexing operation. In one embodiment, the filter 720 is a finite-impulse-response, low-pass filter that also “decimates” or reduces the sample rate of the red and infrared signals 712, 714. The filtered signals 722 are then each normalized by a series combination of a log function 730 and bandpass filter 740. The normalized signals, $\text{RD}(t)$, $\text{IR}(t)$ 742 are coupled to a Fourier transform 750, which provides red frequency spectrum and infrared frequency spectrum outputs, $\text{RD}(\omega)$, $\text{IR}(\omega)$ 612. A demultiplexed infrared signal output 614 is also provided.

[0067] Saturation Calculator

[0068] FIG. 8 shows a graph 800 illustrating idealized spectrums of $\text{RD}(t)$ and $\text{IR}(t)$ 752 (FIG. 7). The graph has an x-axis 810 that corresponds to the frequency of spectral components in these signals and a y-axis 820 that corresponds to the magnitude of the spectral components. The spectral components are the frequency content of $\text{RD}(t)$ and $\text{IR}(t)$, which are plethysmograph signals corresponding to the patient’s pulsatile blood flow, as described below. Thus, the frequencies shown along the x-axis 810, i.e. f_0 , f_1 , f_2 , are the fundamental and harmonics of the patient’s pulse rate. The spectrum of $\text{RD}(t)$, denoted $\text{RD}(\omega)$ 612 (FIG. 7), is shown as a series of peaks, comprising a first peak 832 at a fundamental frequency, f_0 , a second peak 842 at a first harmonic, f_1 and a third peak 852 at a second harmonic, f_2 . Similarly, the spectrum of $\text{IR}(t)$, denoted $\text{IR}(\omega)$ 612 (FIG. 7), is shown as another series of peaks, comprising a first peak 834 at a fundamental frequency, f_0 , a second peak 844 at a first harmonic, f_1 and a third peak 854 at a second harmonic, f_2 . Also shown in FIG. 8 is the ratio of the spectral peaks of $\text{RD}(t)$ and $\text{IR}(t)$, denoted $\text{RD}(\omega)/\text{IR}(\omega)$. This ratio is shown as a first ratio line 838 at the fundamental frequency f_0 , a second ratio line 848 at the first harmonic f_1 and a third ratio line 858 at the second harmonic f_2 .

[0069] The magnitude of these ratio lines $\text{RD}(\omega)/\text{IR}(\omega)$ corresponds to the ratio RD/IR defined by equation (2), and, hence, can be used to determine Sp_aO_2 . This can be seen from Parseval’s relation for a periodic signal, $x(t)$, having a

period T , where X_k is the spectral component at the k th harmonic of $x(t)$:

$$\frac{1}{T} \int_0^T (|x(t)|)^2 dt = \sum_k (|X_k|)^2 \quad (9)$$

[0070] Equation (9) relates the energy in one period of the signal $x(t)$ to the sum of the squared magnitudes of the spectral components. The term $|X_k|^2$ can be interpreted as that part of the energy per period contributed by the k th harmonic. In an ideal measurement, the red and infrared signals are the same to within a constant scale factor, which corresponds to the arterial oxygen saturation. Likewise, the red and infrared spectra are also the same to within a constant scale factor. Thus, in an ideal measurement, all of the ratio lines 838, 848, 858 have substantially the same amplitude. Any differences in the amplitude of the ratio lines is likely due to motion, scattering or other noise contaminations, as discussed further below. Accordingly, any of the $\text{RD}(\omega)/\text{IR}(\omega)$ ratio lines is equivalent to the ratio, RD/IR , of equation (2) and can be used to derive Sp_aO_2 .

[0071] One skilled in the art will recognize that the representations in FIG. 8 are idealized. In particular, in actual measured data, especially if contaminated by noise, the frequencies of the peaks of $\text{RD}(\omega)$ do not correspond exactly to the frequencies of the peaks of $\text{IR}(\omega)$. For example, the fundamental frequency, f_0 , found for $\text{RD}(\omega)$ will often be different from the fundamental frequency, f_0' , found for $\text{IR}(\omega)$ and similarly for the harmonics of f_0 .

[0072] FIG. 9 shows a graph 900 illustrating idealized spectrums $\text{RD}(\omega)$ and $\text{IR}(\omega)$ and associated ratio lines measured with an active pulse sensor. The graph 900 has an x-axis 910 that corresponds to the frequency of spectral components in these signals and a y-axis 920 that corresponds to the magnitude of the spectral components. The spectrum, $\text{RD}(\omega)$, is shown as two series of peaks. One series of peaks 930 occurs at a fundamental frequency, f_{h0} , and associated harmonics, f_{h1} and f_{h2} , of the patient’s pulse (heart) rate. Another series of peaks 940 occurs at a fundamental frequency, f_{p0} , and associated harmonics, f_{p1} and f_{p2} , of the active pulse rate. Similarly, the spectrum, $\text{IR}(\omega)$, is shown as two series of peaks. One series of peaks 950 occurs at a fundamental frequency, f_{h0} , and associated harmonics, f_{h1} and f_{h2} , of the patient’s pulse rate. Another series of peaks 960 occurs at a fundamental frequency, f_{p0} , and associated harmonics, f_{p1} and f_{p2} , of the active pulse rate. Accordingly, there are two series of RD/IR ratio lines. One series of ratio lines 970 are at the patient’s pulse rate and associated harmonics, and another series of ratio lines 980 are at the active pulser rate and associated harmonics.

[0073] Because only the arterial blood is pulsatile at the patient’s pulse rate, the ratio lines 970 are only a function of the arterial oxygen saturation. Accordingly, Sp_aO_2 can be derived from the magnitude of these ratio lines 970, as described above. Further, a modulation level for the active pulse is selected which insignificantly perturbs the arterial blood while providing a measurable venous signal. This is possible because the arterial blood pressure is significantly larger than the venous pressure. The modulation level is regulated as described above with respect to FIG. 2, i.e. the DSP 150, via a pulser drive control 291, sets the magnitude

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of the pulser drive 280 to the pulse inducing mechanism 262. Assuming that the active pulse modulation of the arterial blood is insignificant, only the venous blood is pulsatile at the active pulser rate. Hence, the ratio lines 980 are only a function of the venous oxygen saturation. Accordingly, Sp_vO_2 can be derived from the magnitude of the pulse rate related ratio lines 980 in the same manner as Sp_aO_2 is derived from the magnitude of the pulse rate related ratio lines.

[0074] Scattering

[0075] Propagation of optical radiation through tissue is affected by absorption and scattering processes. The operation of pulse oximeters was described qualitatively above using an analysis based on the Beer-Lambert law of absorption, equation (3). This approach, however, fails to account for the secondary effects of light scattering at pulse oximeter wavelengths. The primary light scatterer in blood is erythrocytes, i.e. red blood cells. A qualitative understanding of the effects of scattering on pulse oximetry is aided by a description of red blood cell properties within flowing blood.

[0076] Human blood is a suspension of cells in an aqueous solution. The cellular contents are essentially all red blood cells, with white cells making up less the $\frac{1}{600}$ th of the total cellular volume and platelets less than $\frac{1}{800}$ th of the total cellular volume. Normally the hematocrit, which is the percentage of the total volume of blood occupied by cells, is about 50% in large vessels and 25% in small arterioles or venules.

[0077] Red blood cells are extremely deformable, taking on various shapes in response to the hydrodynamic stresses created by flowing blood. For example, assuming a laminar blood flow within a vessel, a parabolic velocity profile exists that is greatest in the vessel center and smallest along the vessel walls. Nominally, red blood cells are shaped as biconcave disks with a diameter of 7.6 μm and thickness of 2.8 μm . Exposed to this velocity profile, the red blood cells become parachute-shaped and aligned in the direction of the blood flow. Thus, during systole, transmitted light is scattered by aligned, parachute-shaped cells. During diastole, the light is scattered by biconcave disks having a more or less random alignment.

[0078] The time-varying shape and alignment of the red blood cells can have a significant effect on measured values of oxygen saturation if scattering is ignored. Analogous to the analysis using the Beer-Lambert absorption law, scattering can be qualitatively understood as a function of the scattering coefficients of various tissues. Specifically, the bulk scattering coefficient can be written as:

$$\mu_s = V_b \mu_{sb} + V_t \mu_t \quad (10)$$

[0079] where V_b is the blood volume, μ_b is the scattering coefficient of blood, V_t is the surrounding tissue volume and μ_t is the scattering coefficient of the surrounding tissue. The volume, V_t , and scattering coefficient, μ_t , of the surrounding tissue are time invariant. The blood volume, V_b , however, is pulsatile. The ratio of ratios computation, RD/IR, results in normalization of the time invariant or DC tissue absorption and cancellation of the time varying or AC pulsatile blood volume absorption to yield a number related to oxygen saturation. This computational approach is valid because the absorption coefficients of blood, $\epsilon_{HbO_2, \lambda}$, $\epsilon_{Hb, \lambda}$ given in

equation (4) were assumed to change only slowly over time. The scattering coefficient of blood μ_b , however, is time variant. As described above, this variation is due to the time-varying alignment and shape of the red blood cells. This time variation in the detected intensity of light transmitted through a tissue site is not normalized or canceled by the RD/IR calculation. Further, because the magnitude of the scattering coefficient variations is a function of blood flow, these variations become more pronounced with larger pulses in the blood supply. As a result, scattering produces frequency-dependent magnitude variations in the ratio lines RD(ω)/IR(ω).

[0080] FIG. 9 illustrates the effect of scattering on the spectra of the detected red and infrared intensity waveforms. When these waveforms are transformed into the frequency domain, the time varying component of scattering manifests itself as spreads 978, 988 in the RD/IR ratio lines at each harmonic of the plethysmograph or active pulse rate. The magnitude of the ratio lines 970 at the fundamental and harmonics of the patient's pulse rate varies between a minimum 972 and a maximum 974, resulting in a magnitude spread 978. Similarly, the magnitude of the ratio lines 980 at the fundamental and harmonics of the active pulse rate varies between a minimum 982 and a maximum 984, resulting in a magnitude spread 988. Normally, absent motion artifact or noise contamination, the spread 978, 988 in the ratio lines is quite small, but the magnitude of these spreads 978, 988, increases with larger blood flows or pulse magnitudes. Scattering attributable to an active pulse can be regulated by adjusting the magnitude of the active pulse modulation based upon the amount of spread 978, 988 of the ratio line magnitudes. Thus, the active pulse magnitude can be increased to obtain a larger detected AC signal, but limited to below the point at which scattering becomes significant.

[0081] FIG. 10 depicts an embodiment of the signal processing for determining oxygen saturation from the ratio lines of RD(ω)/IR(ω). The red spectrum RD(ω) 612 and infrared spectrum IR(ω) 612, computed as described above with respect to FIG. 7, are input to a peak detector 1010. The peak detector 1010 separately calculates localized maximums for RD(ω) and IR(ω). The peak detector output 1012 is a series of frequencies corresponding to the patient pulse rate fundamental and harmonics. If an active pulse is used, the peak detector output 1012 is also a series of frequencies corresponding to the active pulse rate. Although the active pulse rate is known, the detected peaks may have been shifted due to noise, motion artifact or other signal contamination. The peak detector output 1012 is coupled to a series combination of peak matcher 1020 and ratio line calculator 1030. The ratio lines RD/IR are calculated by matching the frequency peaks of RD(ω) with the nearest frequency peaks of IR(ω). The ratio lines associated with the pulse rate harmonics 1032 are then separated into a different set from the ratio lines associated with the active pulse harmonics 1034, assuming an active pulse is utilized. An average ratio line for each set 1032, 1034 is calculated by averaging 1060 all ratio lines in a set. The magnitude of the average ratio line r 1062 for the pulse rate set 1032 is then fed to a look-up table (LUT) 1090, which provides an output 622 of the measured value of Sp_aO_2 . Similarly, if an active pulse is used, the magnitude of the average ratio line μ 1064 for the active pulse rate set 1034 is then fed to a LUT 1090, which provides an output 622 of the measured value of Sp_vO_2 . A

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scattering detector **1080** computes the spread **988** (FIG. 9) in the set of ratio lines associated with the active pulse and provides this value **1082** to the DSP **150** (FIG. 2) so that the DSP can set the pulser drive control **291** (FIG. 2) to regulate the magnitude of the active pulse.

[0082] Alternatively, Sp_vO_2 may be measured from respiration-induced pulses in the venous blood, described above, without utilizing an active pulse sensor. Specifically, a series of ratio lines **980** (FIG. 9) would occur at a fundamental frequency, f_{r0} , and associated harmonics, f_{r1} and f_{r2} , of the respiration rate, which is either known from the ventilator frequency or derived from a separate measurement of the natural respiration. As shown in FIG. 10, the ratio lines associated with the respiration rate harmonics **1034** are then separated into a different set from the ratio lines associated with the pulse rate harmonics **1032**. An average ratio line for the respiration rate set **1034** is calculated by averaging **1060** all ratio lines in that set. The magnitude of the average ratio line μ **1064** for the respiration rate set **1034** is then fed to a look-up table (LUT) **1090**, which provides an output **622** of the measured value of Sp_vO_2 .

[0083] Plethysmograph Feature Extractor

[0084] FIG. 11 illustrates the standard plethysmograph waveform **1100**, which can be derived from a pulse oximeter. The waveform **1100** is a visualization of blood volume change in the illuminated peripheral tissue caused by arterial blood flow, shown along the y-axis **1110**, over time, shown along the x-axis **1120**. The shape of the plethysmograph waveform **1100** is a function of heart stroke volume, pressure gradient, arterial elasticity and peripheral resistance. The ideal waveform **1100** displays a broad peripheral flow curve, with a short, steep inflow phase **1130** followed by a 3 to 4 times longer outflow phase **1140**. The inflow phase **1130** is the result of tissue distention by the rapid blood volume inflow during ventricular systole. During the outflow phase **1140**, blood flow continues into the vascular bed during diastole. The end diastolic baseline **1150** indicates the minimum basal tissue perfusion. During the outflow phase **1140** is a dicrotic notch **1160**, the nature of which is disputed. Classically, the dicrotic notch **1160** is attributed to closure of the aortic valve at the end of ventricular systole. However, it may also be the result of reflection from the periphery of an initial, fast propagating, pressure pulse that occurs upon the opening of the aortic valve and that precedes the arterial flow wave. A double dicrotic notch can sometimes be observed, although its explanation is obscure, possibly the result of reflections reaching the sensor at different times.

[0085] FIG. 12 is a graph **1200** illustrating the absorption of light at a tissue site illuminated by a pulse oximetry sensor. The graph **1200** has a y-axis **1210** representing the total amount of light absorbed the tissue site, with time shown along an x-axis **1220**. The total absorption is represented by layers including the static absorption layers due to tissue **1230**, venous blood **1240** and a baseline of arterial blood **1250**. Also shown is a variable absorption layer due to the pulse-added volume of arterial blood **1260**. The profile **1270** of the pulse-added arterial blood **1260** is seen as the plethysmograph waveform **1100** depicted in FIG. 11.

[0086] FIG. 13 illustrates the photoplethysmograph intensity signal **1300** detected by a pulse oximeter sensor. A pulse oximeter does not directly detect absorption, and hence does

not directly measure the standard plethysmograph waveform **1100** (FIG. 11). However, the standard plethysmograph can be derived by observing that the detected intensity signal **1300** is merely an out of phase version of the absorption profile **1270**. That is, the peak detected intensity **1372** occurs at minimum absorption **1272** (FIG. 12), and minimum detected intensity **1374** occurs at maximum absorption **1274** (FIG. 12). Further, a rapid rise in absorption **1276** (FIG. 12) during the inflow phase of the plethysmograph is reflected in a rapid decline **1376** in intensity, and the gradual decline **1278** (FIG. 12) in absorption during the outflow phase of the plethysmograph is reflected in a gradual increase **1378** in detected intensity.

[0087] FIG. 14 illustrates the digital signal processing for plethysmograph feature extraction **630** (FIG. 6). The input **614** is the IR signal output from the demultiplexer **710** (FIG. 7). This signal is shifted into a first-in, first-out (FIFO) buffer, which allows fixed-length portions of the input signal **614** to be processed for feature extraction. The buffered output signal **1412** is coupled to a shape detector **1420**, slope calculator **1430**, feature width calculator **1440** and a notch locator **1450**, which perform the core feature extraction functions. The shape detector **1420** determines if a particular buffered signal portion **1412** contains specific gross features, such as a peak, a valley, an upward slope, a downward slope, a dicrotic notch or a multiple dicrotic notch. A detected shape output **1422** containing one or more flags indicating the gross feature content of the current signal portion **1412** is coupled to the other feature extraction functions **1430**, **1440**, **1450** and to the waveform quality determination functions **1460**, **1470**, **1480**. A slope calculator **1430** determines the amount of positive or negative slope in the signal portion **1412** if the shape detector output **1422** indicates a slope is present. The output slope value **1432** is coupled to the waveform quality functions **1460**, **1470**, **1480** in addition to the feature extraction output **632**. A feature calculator **1440** quantifies a feature in one or more signal portions **1412** specified by the shape detector **1420**, such as the magnitude, the area under, or the width of a peak or notch. The feature calculator output **1442** is a code indicating the feature and its value, which is coupled to the feature extraction output **632**. A feature locator **1450** quantifies the time of occurrence of one or more features of a signal portion **1412** as specified by the shape detector **1420**. The feature locator output **1452**, which is coupled to the feature extraction output **632**, is a code indicating a feature and an associated code indicating time of occurrence in reference to a particular epoch. The feature locator output **1452** allows a determination of the relative location of plethysmograph features in addition to a phase comparison of plethysmographs derived from two or more tissue sites. Another feature extraction output **634**, which is coupled to the multiple parameter processor **640** (FIG. 6), provides an indication of waveform quality. Input signals portions **1412** not having either a sharp downward edge **1460**, a symmetrical peak **1470** or a gradual decline **1480** are not processed further.

[0088] Multiple Parameter Processor

[0089] FIG. 15 illustrates the multiple parameter processing portion **640** (FIG. 6) of the signal processing. A differencing function **1510** has as inputs a first saturation value, Sp_1O_2 , and a second saturation value, Sp_{2O_2} , **622**. The saturation input values **622** can be arterial and venous saturation values from a single data channel, arterial satu-

ration values from two different data channels or venous saturation values from two different data channels. The differences of the saturation value inputs **622** are provided as an output **1514**, which is coupled to a saturation data memory **1520**. The saturation values **622** are also directly coupled to the saturation data memory **1520**. The memory **1520** stores a record of saturation values, SpO_2 , for each channel, delta saturation values, Δsat , for each channel and cross-channel delta saturation values, Δsat_{xy} , as required for a particular application. A flow calculator **1530** utilizes a plethysmograph input **614** or a bio-impedance probe input **1534** to provide a flow value **1538**, which is also coupled to the saturation data memory **1520**. For example, the flow value **1538** may be a perfusion index, PI, defined as follows:

$$PI = (IR_{max} - IR_{min}) / IR_{DC} \quad (11)$$

[0090] where IR_{max} is the maximum value, IR_{min} is the minimum value, and IR_{DC} is the average value of the IR plethysmograph signal **614** (FIG. 7).

[0091] The saturation data memory **1520** provides a buffered output **1522** that is coupled to a numerical display driver **1540**. The numerical display driver **1540** provides an output **642** to a standard display, such as LED or LCD numerical display modules or a CRT monitor. The memory output **1522** is also coupled to a saturation data analyzer **1530**, one function of which calculates a long-term trend of the values in memory **1520**. For example, the saturation data analyzer may average a saturation value over time, or provide samples of the saturation values taken at regular time intervals. The output **1532** can either be numerical, which is coupled to the numerical display driver **1540**, or graphical, which is coupled to the graphical display driver **1570**. The graphical display driver **1570** provides an output **644** to a standard graphical display device, such as LED or LCD graphical display modules or a CRT monitor.

[0092] A pleth data memory **1550** has as inputs the IR plethysmograph signals **614** (FIG. 7) from each data channel and the associated extracted features **632** (FIG. 14). The memory **1550** also has an input indicating waveform quality **634** (FIG. 14). The pleth memory **1550** provides a buffered output **1558** that is coupled to the graphical display driver **1570**, allowing display of the plethysmograph waveforms for each data channel. The memory output **1558** is also coupled to a pleth data analyzer **1560**, one function of which calculates a long-term trend of the plethysmograph and shape parameters in pleth memory **1550**. For example, the pleth data analyzer **1560** may provide an average of particular shape parameters over time. As another example, the pleth data analyzer **1560** may provide a graphic showing an accumulation of many overlaid plethysmographs. The output **1562** can either be numerical, which is coupled to the numerical display driver **1540**, or graphical, which is coupled to the graphical display driver **1570**.

[0093] Another function of the saturation data analyzer **1530** and the pleth data analyzer **1560** is to compare oxygen status and plethysmograph parameters derived from multiple sites in order to isolate noise artifacts and to derive a more accurate estimate of these parameters. For example, it is unlikely that motion artifact will affect each peripheral site in the same manner. If the quality input **634** indicates a noisy plethysmograph for one channel during a particular time period, the pleth data analyzer **1560** can exchange this information **1565** with the saturation data analyzer **1530**.

The saturation data analyzer **1530** can then ignore the saturation data for that channel for that time period in lieu of saturation data from another channel. In a similar fashion, noisy data from multiple channels can be averaged, correlated or otherwise processed to provide an estimate of Sp_aO_2 , Sp_vO_2 or pulse rate, or to provide a plethysmograph that is more accurate than can be derived from a single data channel.

[0094] FIG. 16A illustrates detail of a single-site display screen **180** for the stereo pulse oximeter. The display has a numerical display portion **1610** controlled by the numerical display driver **1540** (FIG. 15) and a graphical display portion **1660** controlled by the graphical display driver **1570** (FIG. 15). The numerical display portion **1610** displays a value for Sp_aO_2 **1620**, Sp_vO_2 **1630** and pulse rate **1640** for a particular tissue site. The graphical display portion **1660** displays a plethysmograph **1662** for the corresponding tissue site, which can be displayed as a single waveform or an accumulated multiple of overlaid waveforms that may reveal a waveform trend. A push button or menu selection allows the user to switch to a display of data from any single one of the multiple tissue sites to which a sensor is attached.

[0095] FIG. 16B illustrates detail of a multi-site display screen **180** for the stereo pulse oximeter. The numerical display portion **1610** displays a value for Sp_aO_2 **1622** and Sp_vO_2 **1632** for a first tissue site. Also displayed is a value for Sp_aO_2 **1624** and Sp_vO_2 **1634** for a second tissue site. In addition, a value for pulse rate **1642** derived from either the first or second tissue site, or both, is displayed. The graphical display portion **1660** displays a first plethysmograph **1664** and a second plethysmograph **1666** corresponding to the first and second tissue sites, respectively. A push button, menu selection allows the user to manually switch between the single site display (FIG. 16A) and the multi-site display (FIG. 16B). Also, a triggering event, such as an alarm based on multiple-site oxygen status parameters, causes the display to automatically switch from the single-site display to the multi-site display, enabling the user better view the conditions that caused the triggering event.

[0096] One of ordinary skill will appreciate many display screens variations from those shown in FIGS. 16A and 16B that are within the scope of this invention. For example, the stereo pulse oximeter could be configured to provide several push button or menu selectable display screens. One display screen might display more than two channels of oxygen status data. Another display screen could display cross-channel parameters such as Δsat_{xy} or a comparison of plethysmograph shape parameters from two channels. One of ordinary skill will also appreciate many variations and modifications of layout and design for the graphical and numerical displays within the scope of this invention.

[0097] Stereo Pulse Oximetry Applications

[0098] Oxygen Titration

[0099] Oxygen is one of the most commonly used drugs in an intensive care unit and is an integral part of all respiratory support. The goal of oxygen therapy is to achieve adequate delivery of oxygen to the tissues without creating oxygen toxicity. Too little oxygen results in organ damage and, in particular, brain damage. Too much oxygen can result in, for example, pulmonary edema and, in neonates, retinopathy of prematurity (ROP). Infants receiving oxygen therapy, in

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particular, must have inspired oxygen concentration and blood oxygen levels monitored closely.

[0100] Oxygen titration in neonates is currently accomplished with either transcutaneous monitoring or monitoring with a conventional pulse oximeter. As mentioned above, transcutaneous monitoring involves the placement of a heated Clark electrode against the skin surface. The electrode is secured to the skin surface with an airtight seal to eliminate contamination by room air gases. The skin surface beneath the electrode is then heated, which opens precapillary sphincters allowing localized arteriolar blood flow beneath the sensor. The so-called T_cO_2 value that is measured correlates well with P_aO_2 . However, there are several drawbacks to this approach. Because the skin surface must be heated, a fifteen minute elapsed time after application is necessary before stable readings are acquired. Further, the required temperature is 43-45° C. (110° F.), with an associated risk of burns. In addition, titration is often accomplished by simply maintaining T_cO_2 within acceptable limits for this parameter, e.g. an equivalent P_aO_2 of 50-80 mm Hg for neonates. However, P_aO_2 alone does not provide an indication of balance between inspired oxygen and the rate of tissue oxygen consumption. If the patient is particularly anemic or hypovolemic, has an abnormal hemoglobin, or a small cardiac output, then oxygen delivery may be inadequate even in the presence of a normal P_aO_2 . Titration with a conventional pulse oximeter is similarly accomplished by maintaining $SpaO_2$ within acceptable limits, which also fails to consider tissue oxygen consumption.

[0101] Oxygen titration can be more adequately monitored with a continuous indication of oxygen consumption, which is equal to oxygen delivery according to Fick's algorithm, as noted above. Further, continuous monitoring of oxygen consumption at a peripheral tissue site, although not necessarily indicative of overall oxygen consumption, may be indicative of an oxygen supply dependency. A measure of peripheral oxygen consumption can be expressed in terms of $\Delta sat = Sp_aO_2 - Sp_vO_2$ and perfusion, which, as noted above, are parameters advantageously provided by the stereo pulse oximeter according to the present invention. Oxygen consumption at a peripheral site is obtained by multiplying the difference between peripheral arterial and venous oxygen content by perfusion at the site.

$$VpO_2 = [O_2 \text{ content(arterial)} - O_2 \text{ content(venous)}] \Phi \quad (12)$$

[0102] where oxygen content is measured in milliliters (ml) of O_2 per deciliters (dl) of blood and Φ denotes perfusion in deciliters per minute. Oxygen content, however, can be expressed in terms of the amount of oxygen bound to the hemoglobin plus the amount of oxygen dissolved in the plasma. The amount of bound oxygen is equal to the hemoglobin concentration, C_{hb} , in grams per deciliter of blood, times the hemoglobin carrying capacity, which is 1.34 milliliters of O_2 per gram of hemoglobin times the hemoglobin oxygen saturation, SO_2 . The amount of dissolved oxygen is simply the partial pressure of oxygen, PO_2 , times the O_2 solubility coefficient in blood, which is 0.003 milliliters of O_2 per deciliter. The sum of these two terms yields:

$$O_2 \text{ content} = 1.34 C_{hb} SO_2 + 0.003 P_{O_2} \quad (13)$$

[0103] Substituting equation (13) into equation (12) yields the following equation for tissue oxygen consumption:

$$VpO_2 = [1.34 C_{hb} (Sp_aO_2 - Sp_vO_2) + 0.003 (P_aO_2 - P_vO_2)] \Phi \quad (14)$$

[0104] Except when the fractional inspired oxygen, FiO_2 , is high, blood plasma plays a minimal role in oxygen delivery. Thus, peripheral oxygen consumption is approximately:

$$VpO_2 = [1.34 C_{hb} \Delta sat] \Phi \quad (15)$$

[0105] In order to illustrate a schema of oxygen titration, it is convenient to characterize the relationship between oxygen supplied at the airway to oxygen consumed at a peripheral tissue site. Specifically, characterization of the relationship between Δsat , Φ and FiO_2 is useful. Assuming constant oxygen consumption at the tissue site, equation (15) is:

$$\Delta sat \Phi = \text{constant} \quad (16)$$

[0106] Equation (16) has a simple analog in electronic circuits, i.e. a variable resistor across a current or voltage source adjusted to maintain constant power. In this analog circuit, the current through the resistor, I , is equivalent to perfusion, the voltage across the resistor, V , is equivalent to Δsat and the constant of equation (16) is equivalent to the constant power, P , consumed by the resistor. The equation representing this electrical analog is:

$$V I = P \quad (17)$$

[0107] FIG. 17A shows a graph 1701 that depicts a family of curves each corresponding to different values of P in equation (17). The graph 1701 has an x-axis 1710 indicating current, I , and a y-axis 1720 indicating voltage, V . A first curve 1730 shows V versus I for a constant power, P , of 0.5 watts; a second curve 1740 shows V versus I for a constant P of 1 watt; and a third curve 1750 shows V versus I for a constant P of 2 watts. Using the analogy between equations (16) and equation (17), whenever Φ (current) is small, the Δsat (voltage) is large and vice-a-versa. Also, a change in consumption (power) causes a shift in the curve along with a change in its curvature. That is, if the body suddenly changes its metabolic rate at the peripheral tissue site, the curve will accordingly shift up or shift down and will change its shape. Equation (16) and the analogous constant consumption curves of FIG. 17A assume a supply independent condition, i.e. that peripheral oxygen consumption is satisfied by peripheral oxygen delivery. If the peripheral tissue site is starved for oxygen, then the locus of points for Δsat versus Φ is quite different from a hyperbola. The amount of tissue oxygen extraction is at a maximum and is independent of Φ . Accordingly Δsat is at a maximum and independent of Φ . The above analysis provides insight into the relationship between Δsat and Φ . The relationship between Δsat and FiO_2 can also be characterized.

[0108] FIG. 17B shows a graph 1702 of saturation along a y-axis 1760 and fractional inspired oxygen along an x-axis 1770. A curve of Sp_aO_2 1780 and a curve of Sp_vO_2 1790 are depicted versus FiO_2 . The difference between these curves 1780, 1790 yields Δsat 1785 versus FiO_2 . When FiO_2 is zero 1772, oxygen saturation and, hence, both Sp_aO_2 1780 and Sp_vO_2 1790 are zero. As FiO_2 is increased, Sp_aO_2 1780 also increases until virtually reaching 100 percent saturation 1762. As FiO_2 increases further, Sp_aO_2 1780 stays at virtually 100 percent saturation 1762. As FiO_2 is increased from zero 1772, Sp_vO_2 1790 also increases. In this low FiO_2 region 1774, the peripheral tissue site is supply dependent and Δsat 1785 also increases. At a certain point, the tissue site oxygen demand is met by supply. In this supply independent region 1776, oxygen consumption is constant and

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equation (16) is valid. Also, Δsat 1785 is at a constant maximum, which is a function of the metabolism at the tissue site. As FiO_2 increases further, eventually the partial pressure of oxygen becomes significant and the second term of equation (14) must be considered. In this high FiO_2 region 1778, Δsat 1785 decreases because some of the tissue oxygen consumption is supplied by oxygen dissolved in the plasma.

[0109] FIG. 17C shows a graph 1704 of saturation difference along a y-axis 1764 and fractional inspired oxygen along an x-axis 1770. A curve of Δsat 1786 is depicted versus FiO_2 , corresponding to the region Δsat 1785 depicted in FIG. 17B. The curve 1786 has a first deflection point 1766 occurring at the transition between the low FiO_2 region 1774 (FIG. 17B) and the supply independent region 1776 (FIG. 17B). The curve 1786 also has a second deflection point 1768 occurring at the transition between the supply independent region 1776 (FIG. 17B) and the high FiO_2 region 1778 (FIG. 17B). The curve 1786 illustrates how the trend for Δsat , as measured by the stereo pulse oximeter, can be used to accurately titrate oxygen. The goal of oxygen titration is to supply sufficient oxygen to supply tissue demand and avoid unnecessarily high amounts of FiO_2 . Thus, the Δsat parameter should be monitored so that FiO_2 is adjusted between the two deflection points 1766, 1768. For neonates, FiO_2 should be adjusted just beyond the first deflection point 1766. For adults, FiO_2 should be adjusted just before the second deflection point 1768.

[0110] FIG. 18 illustrates a graph having a three-dimensional surface 1800 generally depicting the relationship between Δsat , Φ and FiO_2 from the combined graphs of FIGS. 17A and 17C. The graph has an x-axis 1810 showing FiO_2 , a y-axis 1820 showing Φ and a z-axis 1830 showing Δsat . The surface 1800 has a supply dependent region 1840, a perfusion-limited region 1850, a constant consumption region 1860 and a plasma dependent region 1870. The surface describes the oxygen status of a peripheral tissue site. The supply dependent region 1840 corresponds to the low FiO_2 region 1774 (FIG. 17B) described above. That is, inspired oxygen into the lungs is so low that, at the tissue site, oxygen extraction by the tissues is limited by oxygen delivery, and Δsat falls rapidly as FiO_2 is reduced. The perfusion-limited region 1850 along the x-axis 1810 represents a low perfusion state where equation (16) is not valid. That is, perfusion at the tissue site is so low that oxygen extraction by the tissues is at a maximum, and, hence, Δsat is at a maximum and is independent of FiO_2 . A cross-section of the surface taken parallel to the y-axis 1820 yields a hyperbole-shaped constant consumption region 1860, consistent with the constant metabolic rate curves illustrated above with respect to FIG. 17A. The plasma dependent region 1870 corresponds to the high FiO_2 region 1778 (FIG. 17B) described above. That is, inspired oxygen into the lungs is so high that the tissue site is partially dependent on oxygen dissolved in the plasma. The surface 1800 illustrates that perfusion should be monitored simultaneously with Δsat to avoid the perfusion-limited region 1850, where Δsat is an unresponsive indicator of FiO_2 , and to avoid misinterpreting hyperbolic changes in Δsat that result from changes in perfusion.

[0111] Persistent Pulmonary Hypertension in Neonates

[0112] FIG. 19 illustrates the heart/lung circulation of a hypertensive neonate. Persistent Pulmonary Hypertension in

Neonates (PPHN) is a neonatal condition with persistent elevation of pulmonary vascular resistance and pulmonary artery pressure. Shown is a neonatal heart 1902 and a portion of a neonatal lung 1904. The pulmonary artery 1910 that normally feeds oxygen depleted "blue" blood from the right ventricle 1920 to the lung 1904 is constricted. The back pressure from the constricted artery 1910 results in a right-to-left shunting of this oxygen depleted blood through the ductus arteriosus 1930, causing it to mix with oxygen rich "red" blood flowing through the descending aorta 1940. PPHN treatment options include vasodilators, such as nitric oxide (NO). Inhaled exogenous NO causes a dose-dependent decrease in pulmonary artery pressure and pulmonary vascular resistance, as well as a parallel increase in pulmonary blood flow, without affecting systemic arterial pressure. However, the response to NO therapy is a function of the cause of the PPHN as well as the time elapsed before initiation of therapy. Potential toxic effects of NO dictate the proper titration of NO gas. Too little NO may not effectively relieve pulmonary hypertension, and too much NO may cause cellular injury or toxicity. NO therapy is currently monitored using intermittent ultrasound imaging and/or in vitro blood gas measurements. The drawbacks to these techniques are noncontinuous monitoring and disturbances to the neonate that can exacerbate or not reflect the hypertension in the non-disturbed state.

[0113] The stereo pulse oximeter according to the present invention allows noninvasive, continuous monitoring of a neonate for detection and managed treatment of PPHN that does not disturb the patient. A right hand sensor 130 (FIG. 1) provides arterial oxygen saturation and a plethysmograph for blood circulating from the left ventricle 1950 through the innominate artery 1960, which supplies the right subclavian artery. Because the innominate artery 1960 is upstream from the shunt at the ductus arteriosus 1930, the oxygen saturation value and plethysmograph waveform obtained from the right hand are relatively unaffected by the shunt and serve as a baseline or reference for comparison with readings from other tissue sites. Alternatively, a reference sensor can be placed on a facial site, such as an ear, the nose or the lips. These sites provide arterial oxygen saturation and a plethysmograph for blood circulating from the left ventricle 1950 to the innominate artery 1960, which supplies the right common carotid artery (not shown), or to the left common carotid artery 1965.

[0114] A foot sensor 120 (FIG. 1) provides oxygen status for blood supplied from the descending aorta 1940. The shunt 1930 affects both the oxygen saturation and the blood flow in the descending aorta 1940. As stated above, the shunt 1930 causes oxygen-depleted blood to be mixed with oxygen-rich blood in the descending aorta 1940. Because the descending aorta 1940 supplies blood to the legs, the oxygen saturation readings at the foot will be lowered accordingly. The PPHN condition, therefore, is manifested as a higher arterial oxygen saturation at the right hand reference site and a lower saturation at the foot site.

[0115] The shunt also allows a transitory left to right flow during systole, which distends the main pulmonary artery 1980 as the result of the blood flow pressure at one end from the right ventricle and at the other end from the aortic arch 1990. A left-to-right flow through the shunt 1930 into the distended artery 1980 alters the flow in the descending aorta 1940 and, as a result, the plethysmograph features measured

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at the foot. The PPHN condition, therefore, also is manifested as a plethysmograph with a narrow peak and possibly a well-defined dicrotic notch at the left hand baseline site and a broadened peak and possibly no notch at the foot site.

[0116] An optional left hand sensor **110** (FIG. 1) provides oxygen status for blood circulating from the left ventricle through the left subclavian artery **1970** that supplies the left arm. Because the left subclavian artery **1970** is nearer the shunt **1930** than the further upstream innominate artery **1960**, it may experience some mixing of deoxygenated blood and an alteration in flow due to the shunt **1930**. The PPHN condition, therefore, may also be manifested as a reduced saturation and an altered plethysmograph waveform at the left hand site as compared with the right hand baseline site, although to a lesser degree than with a foot site. Thus, the PPHN condition can be detected and its treatment monitored from Δsat and plethysmograph morphology comparisons between a right hand baseline sensor site and one or more other sites, such as the left hand or foot.

[0117] Patent Ductus Arteriosus

[0118] FIG. 20 illustrates the fetal heart/lung circulation. Shown is a fetal heart **2002** and a portion of a fetal lung **2004**. The lung **2004** is non-functional and fluid-filled. Instead, oxygenated blood is supplied to the fetus from gas-exchange in the placenta with the mother's blood supply. Specifically, oxygenated blood flows from the placenta, through the umbilical vein **2006** and into the right atrium **2022**. There, it flows via the foramen **2024** into the left atrium **2052**, where it is pumped into the left ventricle **2050** and then into the aortic trunk **2092**. Also, oxygenated blood is pumped from the right atrium **2022** into the right ventricle **2020** and directly into the descending aorta **2040** via the main pulmonary artery **2080** and the ductus arteriosus **2030**. Normally, the ductus arteriosus **2030** is only open (patent) during fetal life and the first 12 to 24 hours of life in term infants. The purpose of the ductus arteriosus **2030** is to shunt blood pumped by the right ventricle **2020** past the constricted pulmonary circulation **2010** and into the aorta **2040**.

[0119] FIG. 21 illustrates a neonatal heart **2002** with a patent ductus arteriosus **2030**. The ductus arteriosus frequently fails to close in premature infants, allowing left-to-right shunting, i.e. oxygenated "red" blood flows from the aorta **2040** to the now unobstructed pulmonary artery **2010** and recirculates through the lungs **2004**. A persistent patent ductus arteriosus (PDA) results in pulmonary hyperperfusion and an enlarged right ventricle **2020**, which leads to a variety of abnormal respiratory, cardiac and genitourinary symptoms. Current PDA diagnosis involves physical examination, chest x-ray, blood gas analysis, echocardiogram, or a combination of the above. For example, large PDAs may be associated with a soft, long, low-frequency murmur detectable with a stethoscope. As another example, two-dimensional, color Doppler echocardiography may show a retrograde flow from the ductus arteriosus **2030** into the main pulmonary artery **2080**. Once a problematic PDA is detected, closure can be effected medically with indomethacin or ibuprofen or surgically by ligation. Multiple doses of indomethacin are commonplace but can still result in patency, demanding ligation. A drawback to current diagnostic techniques is that clinical symptoms of a PDA can vary on an hourly basis, requiring extended and inherently intermittent testing.

[0120] The stereo pulse oximeter according to the present invention allows for continuous evaluation of PDA symptoms using non-invasive techniques. A right hand sensor **130** (FIG. 1) provides arterial oxygen saturation and a plethysmograph for blood circulating from the left ventricle **2050** through the innominate artery **2160**, which supplies the right subclavian artery leading to the right arm. Because the innominate artery **2160** is upstream from the shunt at the ductus arteriosus **2030**, the oxygen saturation value and plethysmograph waveform obtained from the right hand are relatively unaffected by the shunt and serve as a baseline for comparison with readings from other tissue sites.

[0121] A foot sensor **120** (FIG. 1) provides oxygen status for blood supplied from the descending aorta **2040**. Unlike a PPHN condition, the shunt **2030** does not affect oxygen saturation in the descending aorta **2040**, because the relatively low pressure in the pulmonary artery **2010** does not allow a mixing of deoxygenated blood into the relatively high pressure flow of oxygenated blood in the aorta **2040**. However, like a PPHN condition, the shunt **2030** does affect the aortic flow. In particular, the shunt allows a transitory left-to-right flow during systole from the high pressure aorta **2040** to the low pressure pulmonary circulation **2010**. This left-to-right flow through the shunt **1930** alters the flow in the descending aorta **1940** and, as a result, the plethysmograph features measured at the foot. The PDA condition, therefore, is manifested as a normal plethysmograph with a characteristically narrow peak and well-defined dicrotic notch at the right-hand baseline site compared with a damped plethysmograph with a broadened peak and reduced or missing notch at the foot site. Further, the foot site waveform is phase shifted from the baseline waveform. These plethysmograph differences are accompanied by comparable arterial oxygen saturation values between the right-hand site and the foot site.

[0122] An optional left hand sensor **110** (FIG. 1) provides oxygen status for blood circulating from the left ventricle through the left subclavian artery **2170** that supplies the left arm. Because the left subclavian artery **2170** is nearer the shunt **2030** than the further upstream innominate artery **2160**, it may experience some alteration in flow due to the shunt **2030**. The PDA condition, therefore, may also be manifested as an altered plethysmograph waveform at a left hand site as compared with the right hand baseline site, although to a lesser degree than with a foot site. Thus, the PDA condition can be detected and its treatment monitored from $\Delta\text{sat}_{xy} \neq 0$ and plethysmograph morphology and phase comparisons between a right hand baseline sensor site and one or more other sites, such as the left hand or foot. One of ordinary skill will recognize that multiple site comparisons using the stereo pulse oximeter of the current invention may also be used to detect other cardiac abnormalities that cause mixing of oxygenated and deoxygenated blood, such as a ventricular hole or a patent foramen. Further, abnormal mixing of oxygenated and deoxygenated blood may also be manifested in measurements provided by the stereo oximeters other than Δsat_{xy} and Δpleth_{xy} as described above. For example, an inversion in Δsat at a particular tissue site, i.e., Sp_vO_2 being larger than Sp_aO_2 at that site, would indicate such an abnormal condition.

[0123] Aortic Coarctation

[0124] Coarctation of the aorta is a congenital cardiac anomaly in which obstruction or narrowing occurs in the

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distal aortic arch or proximal descending aorta. It occurs as either an isolated lesion or coexisting with a variety of other congenital cardiac anomalies, such as a PDA. If the constriction is preductal, lower-trunk blood flow is supplied predominantly by the right ventricle via the ductus arteriosus, and cyanosis, i.e. poorly oxygenated blood, is present distal to the coarctation. This can be detected by the stereo pulse oximeter from a comparison of Sp_aO_2 between an upper body and a lower body site. If the constriction is postductal, blood supply to the lower trunk is supplied via the ascending aorta. Differential plethysmographs between the upper and lower extremities may not exist if the ductus is widely patent. If the ductus closes, however, this condition can be detected by the stereo pulse oximeter as a reduced amplitude and phase delay between the plethysmographs measured at a lower body site with respect to an upper body site.

[0125] The stereo pulse oximeter has been disclosed in detail in connection with various embodiments of the present invention. These embodiments are disclosed by way of examples only and are not to limit the scope of the present invention, which is defined by the claims that follow. One of ordinary skill in the art will appreciate many variations and modifications within the scope of this invention.

What is claimed is:

1. A physiological monitor comprising:
 - a sensor interface in communication with a peripheral tissue site and having an interface output responsive to light transmitted through said site; and
 - a signal processor in communication with said sensor interface output that provides a plurality of parameters corresponding to oxygen status or plethysmograph features of said site.
2. The physiological monitor of claim 1 wherein said parameters comprise a first value and a second value related to said site.
3. The physiological monitor of claim 2 wherein said first value is an arterial oxygen saturation and said second value is a venous oxygen saturation.
4. The physiological monitor of claim 3 wherein said parameters further comprise the difference between said arterial oxygen saturation and said venous oxygen saturation.
5. The physiological monitor of claim 3 wherein said second value is derived from an active pulse generated at said site.
6. The physiological monitor of claim 5 wherein:
 - said signal processor output further comprises a scattering indicator corresponding to said site; and
 - said sensor interface further comprises a pulser drive controlling the amplitude of said active pulse, said drive responsive to said indicator.
7. The physiological monitor of claim 2 wherein at least one of said values is an indication of perfusion.
8. A physiological monitor comprising:
 - a plurality of sensor interfaces each in communications with one of a plurality of peripheral tissue sites, each of said interfaces having one of a plurality of outputs responsive to light transmitted through a corresponding one of said sites; and

a signal processor in communication with said sensor interface outputs, said processor having an output comprising a plurality of parameters corresponding to oxygen status or plethysmograph features of said sites.

9. The physiological monitor of claim 8 wherein said parameters comprise a first value relating to a first of said peripheral tissue sites and a second value relating to a second of said peripheral tissue sites.

10. The physiological monitor of claim 9 wherein said first value and said second value are arterial oxygen saturations.

11. The physiological monitor of claim 9 wherein said first value and said second value are plethysmograph waveform phases.

12. The physiological monitor of claim 8 further comprising a sensor attachable to each of said sites, said sensor comprising:

a plurality of emitters and a plurality of detectors, at least one of said emitters and at least one of said detectors being associated with each of said sites;

a connector in communications with said sensor interfaces; and

a plurality of signal paths attached between said emitters and said detectors at a first end and said connector at a second end.

13. A physiological monitoring method comprising the steps of:

deriving a reference parameter and a test parameter from oxygen status measured from at least one of a plurality of peripheral tissue sites; and

comparing said reference parameter to said test parameter so as to determine a patient condition.

14. The physiological monitoring method according to claim 13 wherein said reference parameter is a first oxygen saturation value and said test parameter is a second oxygen saturation value and said comparing step computes a delta oxygen saturation value equal to the arithmetic difference between said first oxygen saturation value and said second oxygen saturation value.

15. The physiological monitoring method of claim 14 wherein said reference parameter is an arterial oxygen saturation measured at a particular one of said sites, said test parameter is a venous oxygen saturation measured at said particular one site and said comparing step determines the presence of a patient abnormality based on a negative delta oxygen saturation value.

16. The physiological monitoring method according to claim 14 wherein said reference parameter is an arterial oxygen saturation value at a particular one of said sites, said test parameter is a venous oxygen saturation value at said particular site, said method further comprising the steps of:

monitoring changes in said delta oxygen saturation as a function of inspired oxygen; and

adjusting inspired oxygen so that said delta oxygen saturation value remains constant with changes in inspired oxygen.

17. The physiological monitoring method according to claim 14 wherein said reference parameter is a first arterial oxygen saturation value at a first of said sites, said test parameter is a second arterial oxygen saturation value at a second of said sites, said method further comprising the step

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of detecting a patent ductus arteriosus when said delta saturation value is substantially zero.

18. The physiological monitoring method according to claim 14 wherein said reference parameter is a first arterial oxygen saturation value at a first of said sites, said test parameter is a second arterial oxygen saturation value at a second of said sites, said method further comprising the step of detecting pulmonary hypertension when said delta saturation value is substantially non-zero.

19. The physiological monitoring method according to claim 14, wherein said reference parameter is a first arterial oxygen saturation value at a first of said sites, said test parameter is a second arterial oxygen saturation value at a second of said sites, said method further comprising the step of detecting an aortic coarctation when said delta saturation is substantially non-zero.

20. The physiological monitoring method according to claim 13, wherein said reference parameter is a plethysmograph feature measured at a first of said sites, said test parameter is a plethysmograph feature measured at a second of said sites.

21. The physiological monitoring method according to claim 20, wherein said comparing step determines the phase difference between plethysmographs at said first site and said second site.

22. The physiological monitoring method according to claim 21, further comprising the step of detecting a patent ductus arteriosus when said phase difference is substantially non-zero.

23. The physiological monitoring method according to claim 21, further comprising the step of detecting an aortic coarctation when said phase difference is substantially non-zero.

24. The physiological monitoring method according to claim 20, wherein said comparing step determines a relative amount of damping between plethysmographs at said first site and said second site.

25. The physiological monitoring method according to claim 24, further comprising the step of detecting a patent ductus arteriosus when said damping is substantially non-zero.

26. The physiological monitoring method according to claim 24, further comprising the step of detecting an aortic coarctation when said damping is substantially non-zero.

27. The physiological monitoring method according to claim 24, further comprising the step of detecting pulmonary hypertension when said damping is substantially non-zero.

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EXHIBIT 7

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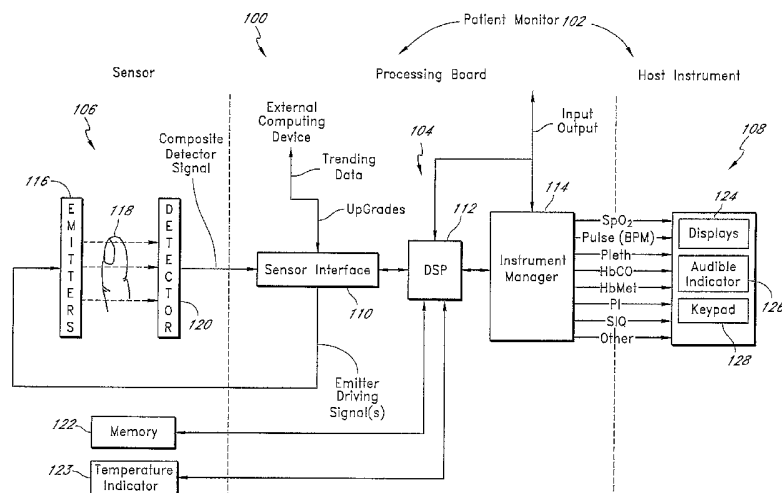
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(54) Title: NONINVASIVE MULTI-PARAMETER PATIENT MONITOR



(57) Abstract: Embodiments of the present disclosure include a handheld multi-parameter patient monitor capable of determining multiple physiological parameters from the output of a light sensitive detector capable of detecting light attenuated by body tissue. For example, in an embodiment, the monitor is capable of advantageously and accurately displaying one or more of pulse rate, plethysmograph data, perfusion quality, signal confidence, and values of blood constituents in body tissue, including for example, arterial carbon monoxide saturation ("HbCO"), methemoglobin saturation ("HbMet"), total hemoglobin ("Hbt"), arterial oxygen saturation ("SpO2"), fractional arterial oxygen saturation ("SpaO2"), or the like. In an embodiment, the monitor advantageously includes a plurality of display modes enabling more parameter data to be displayed than the available physical display real estate.

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Noninvasive Multi-Parameter Patient MonitorPriority Claim to Related Provisional Applications

[0001] The present application claims priority benefit under 35 U.S.C. § 119(e) to U.S. Provisional Patent Application Serial No. 60/657,596, filed March 1, 2005, entitled "*Multiple Wavelength Sensor*," No. 60/657,281, filed March 1, 2005, entitled "*Physiological Parameter Confidence Measure*," No. 60/657,268, filed March 1, 2005, entitled "*Configurable Physiological Measurement System*," and No. 60/657,759, filed March 1, 2005, entitled "*Noninvasive Multi-Parameter Patient Monitor*." The present application incorporates the foregoing disclosures herein by reference.

Incorporation by Reference of Related Utility Applications

[0002] The present application is related to the following copending U.S. utility applications:

	App. Sr. No.	Filing Date	Title	Atty Dock.
1	11/####,###	March 1, 2006	Multiple Wavelength Sensor Emitters	MLR.002A
2	11/####,###	March 1, 2006	Multiple Wavelength Sensor Equalization	MLR.003A
3	11/####,###	March 1, 2006	Multiple Wavelength Sensor Substrate	MLR.004A
4	11/####,###	March 1, 2006	Multiple Wavelength Sensor Interconnect	MLR.005A
5	11/####,###	March 1, 2006	Multiple Wavelength Sensor Attachment	MLR.006A
6	11/####,###	March 1, 2006	Multiple Wavelength Sensor Drivers	MLR.009A
7	11/####,###	March 1, 2006	Physiological Parameter Confidence Measure	MLR.010A
8	11/####,###	March 1, 2006	Configurable Physiological Measurement System	MLR.011A
9	11/####,###	March 1, 2006	Noninvasive Multi-Parameter Patient Monitor	MLR.012A
10	11/####,###	March 1, 2006	Noninvasive Multi-Parameter Patient Monitor	MLR.013A
11	11/####,###	March 1, 2006	Noninvasive Multi-Parameter Patient Monitor	MLR.014A

[0003] The present application incorporates the foregoing disclosures herein by reference.

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Field of the Disclosure

[0004] The present disclosure relates to the field of noninvasive patient monitors. More specifically, the disclosure relates to monitors displaying measurements derived using signals from optical sensors.

Background

[0005] Spectroscopy is a common technique for measuring the concentration of organic and some inorganic constituents of a solution. The theoretical basis of this technique is the Beer-Lambert law, which states that the concentration c_i of an absorbent in solution can be determined by the intensity of light transmitted through the solution, knowing the pathlength d_λ , the intensity of the incident light $I_{0,\lambda}$, and the extinction coefficient $\epsilon_{i,\lambda}$ at a particular wavelength λ . In generalized form, the Beer-Lambert law is expressed as:

$$I_\lambda = I_{0,\lambda} e^{-d_\lambda \cdot \mu_{0,\lambda}} \quad (1)$$

$$\mu_{0,\lambda} = \sum_{i=1}^n \epsilon_{i,\lambda} \cdot c_i \quad (2)$$

[0006] where $\mu_{0,\lambda}$ is the bulk absorption coefficient and represents the probability of absorption per unit length. The minimum number of discrete wavelengths that are required to solve Equations 1-2 are the number of significant absorbers that are present in the solution.

[0007] A practical application of this technique is pulse oximetry, which utilizes a noninvasive sensor to measure oxygen saturation (SpO_2) and pulse rate. In general, the sensor has light emitting diodes (LEDs) that transmit optical radiation of red and infrared wavelengths into a tissue site and a detector that responds to the intensity of the optical radiation after absorption (e.g., by transmission or transreflectance) by pulsatile arterial blood flowing within the tissue site. Based on this response, a processor determines measurements for SpO_2 , pulse rate, and can output representative plethysmographic waveforms. Thus, "pulse oximetry" as used herein encompasses its broad ordinary meaning known to one of skill in the art, which includes at least those noninvasive procedures for measuring parameters of circulating blood through spectroscopy. Moreover, "plethysmograph" as used herein (commonly referred to as "photoplethysmograph"), encompasses its broad ordinary meaning known to one

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of skill in the art, which includes at least data representative of a change in the absorption of particular wavelengths of light as a function of the changes in body tissue resulting from pulsing blood.

[0008] Pulse oximeters capable of reading through motion induced noise are available from Masimo Corporation ("Masimo") of Irvine, California. Moreover, portable and other oximeters capable of reading through motion induced noise are disclosed in at least U.S. Pat. Nos. 6,770,028, 6,658,276, 6,157,850, 6,002,952, and 5,769,785. Read which are owned by Masimo, and are incorporated by reference herein. Such reading through motion oximeters have gained rapid acceptance in a wide variety of medical applications, including surgical wards, intensive care and neonatal units, general wards, home care, physical training, and virtually all types of monitoring scenarios.

Summary of the Disclosure

[0009] Despite the success of read through motion oximeter systems, there is a need to provide patient monitors capable of displaying multiple physiological parameters, other than or in addition to SpO₂, plethysmograph waveforms, or pulse rates. For example, in accessing a patient's condition, caregivers often desire knowledge of other blood constituents, including for example, a percent value for arterial carbon monoxide saturation ("HbCO") or a percent value for methemoglobin saturation ("HbMet") or the like. For example, in an embodiment, the display advantageously displays one or more of the following: pulse rate, plethysmograph waveform data, perfusion index, values of blood constituents in body tissue, including for example, HbCO, HbMet, total hemoglobin ("Hbt"), arterial oxygen saturation ("SpO₂"), fractional arterial oxygen saturation ("SpaO₂"), or the like. In other embodiments, the monitor may advantageously and accurately determine values for one or more of HbO₂, Hb, blood glucose, water, the presence or absence of therapeutic drugs (aspirin, Dapson, nitrates, or the like) or abusive/recreational drugs (methamphetamine, alcohol, steroids, or the like), concentrations of carbon dioxide ("CO₂") or oxygen ("O"), ph levels, bilirubin, perfusion quality, signal quality or the like. Accordingly, the present disclosure includes a multi-parameter patient monitor capable of

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determining one or more of the foregoing parameters, other than or in addition to, SpO₂, plethysmograph waveforms, or perfusion quality index.

[0010] In an embodiment, the display of a noninvasive multi-parameter patient monitor advantageously includes a plurality of display modes enabling more parameter data to be displayed than the available physical display area or real estate. In an embodiment, a user may cycle different parameter values through an area of the display common to both parameters even when one parameter is shifted, through, for example, actuation of a user input key. The patient monitor may also display different parameters as color-coded. For example, when the following measured parameters are within “normal” ranges, SpO₂ may be displayed red, pulse rate (BPM) may be displayed green, HbCO may be displayed orange, HbMet may be displayed blue, or the like. In an embodiment, measured values of SpO₂ may be displayed in white, BPM may be displayed in yellow green or aquamarine, PITM may be displayed in violet, Hbt may be displayed in grass green, HbMet may be displayed in blue or light blue, HbCO may be displayed in orange, and SpaO₂ may be displayed in electric blue.

[0011] Moreover, parameter trend data may also be displayed using the same or similar color coding, especially when multiple trends are displayed on one or more display graphs. In addition, more coarse or gross parameter indications may be displayed for quick reference to indicate to a caregiver whether any of a variety of monitored parameters, such as, for example, SpO₂, HbCO or HbMet is within acceptable ranges. The monitor may advantageously include additional display information, such as, for example, parametric displays where one parameter is displayed as a function of another, three dimensional displays (for example, extending a parametric display along time or an additional parameter), directional indicators predicting where a parameter is likely heading or reporting a general direction a parameters has been trending, or the like.

[0012] In addition to the foregoing, caregivers often desire to more closely monitor parameters that are close to, approaching, or beyond normal safe thresholds. In an embodiment, the patient monitor provides an indication that the caregiver should change display modes to view more critical monitored parameters. In alternative embodiments, the patient monitor automatically

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changes display modes to show parameters moving closer to or beyond normal thresholds.

[0013] In an embodiment, the patient monitor includes an audible or visual indication of a type of sensor communicating with the monitor. For example, the monitor may determine how many wavelengths a particular attached sensor will emit through communication with memory devices associated with the attached sensor or cable.

[0014] Additional embodiments include audio or visual alarms for each of multiple monitored parameters, combinations of parameters, an indication of perfusion in the tissue of the measurement site, an indication of the confidence the signal processing has in its output measurements, or the like.

[0015] For purposes of summarization, certain aspects, advantages and novel features are described herein. Of course, it is to be understood that not necessarily all such aspects, advantages or features need to be present in any particular embodiment.

Brief Description of the Drawings

[0016] The drawings and the associated descriptions are provided to illustrate embodiments of the disclosure and not to limit the scope of the claims.

[0017] **Fig. 1** illustrates a block diagram of an exemplary embodiment of a patient monitoring system including a sensor and a multi-parameter patient monitor.

[0018] **Fig. 2** illustrates a top elevation view of an exemplary handheld noninvasive multi-parameter patient monitor capable of displaying at least HbCO, such as, for example, the patient monitor of **Fig. 1**.

[0019] **Fig. 3** illustrates an exemplary display of the patient monitor of **Fig. 2**.

[0020] **Fig. 4** illustrates the display of **Fig. 3** showing measured values of SpO₂, BPM, perfusion, and type of sensor according to an exemplary embodiment of the patient monitor of **Fig. 1**.

[0021] **Fig. 5** illustrates the display of **Fig. 3** showing measured values of HbCO, perfusion, and type of sensor according to an exemplary embodiment of the patient monitor of **Fig. 1**.

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[0022] **Fig. 6** illustrates the display of **Fig. 3** showing measured values of SpO₂, HbCO, BPM, perfusion, and type of sensor, according to an exemplary embodiment of the patient monitor of **Fig. 1**.

[0023] **Fig. 7** illustrates a top elevation view of an exemplary handheld noninvasive multi-parameter patient monitor capable of displaying at least HbCO and HbMet, such as, for example, the patient monitor of **Fig. 1**.

[0024] **Fig. 8** illustrates an exemplary display of the patient monitor of **Fig. 7**.

[0025] **Fig. 9** illustrates the display of **Fig. 8** showing measured values of SpO₂, BPM, HbCO, HbMet, and type of sensor according to an exemplary embodiment of the patient monitor of **Fig. 1**.

[0026] **Fig. 10** illustrates the display of **Fig. 8** showing measured values of HbCO, HbMet, and type of sensor according to an exemplary embodiment of the patient monitor of **Fig. 1**.

[0027] **Fig. 11A** illustrates a perspective view of an exemplary noninvasive multi-parameter patient monitor such as, for example, the patient monitor of **Fig. 1**.

[0028] **Figs. 11B – 11H** illustrate display screens of the patient monitor of **Fig. 11A**.

Detailed Description of Preferred and Alternative Embodiments

[0029] Embodiments of the present disclosure include a portable or other multi-parameter patient monitor capable of determining multiple physiological parameters from one or more signals output from one or more light sensitive detectors capable of detecting light attenuated by body tissue carrying pulsing blood. For example, in an embodiment, the monitor advantageously and accurately determines a wide variety of physiological parameters or other calculations as discussed above.

[0030] In an embodiment, the display of patient monitor advantageously includes a plurality of display modes enabling more parameter data to be displayed than the available physical display real estate. For example, the patient monitor may include one or more user input keys capable of toggling through measurement data. In an embodiment, the displays include mode

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indicators providing caregivers easily identifiable visual queues, such as LED's, text, icons, or other indicia providing readily identifiable queues as to which parameter is being displayed. In an embodiment, the display may shift, may be parameter color-coded, or the like to further ensure quick comprehension of which measured parameter is the displayed parameter. For example, in an embodiment, the monitor displays SpO₂ in white, pulse rate (BPM) in green, HbCO in orange, and HbMet in blue when the respective measured parameter is within a "normal" range.

[0031] In an embodiment, the patient monitor provides an indication that the caregiver should change display modes to view more critical or time sensitive measured parameters, specific caregiver selected parameters, or the like. For example, the patient monitor may advantageously sound audio or visual alarms that alert the caregiver to particular one or more of worsening parameters, parameters changing in a predetermined pattern or rate, parameters stabilizing below user defined or safe thresholds, caregiver selected parameters, or the like. The monitor may also use alerts that provide audio or visual indications of the severity of the condition, severity of the change, or the like. In alternative embodiments, the patient monitor may automatically change display modes when a particular parameter crosses one or more thresholds. For example, a patient monitor may be displaying a first parameter, such as a plethysmograph, and upon determining measurements indicating that HbMet is trending toward an alarm condition, the monitor may automatically switch from displaying the first parameter to the alarming parameter, or in this case, a trend of the alarming parameter.

[0032] In an embodiment, a switch is provided to allow a user to switch displays to view an alarming measurement. In an embodiment, during an alarm condition, a parameter display may switch to a trend graph in the same or different color, line weight, flash, flash rate, intensity, size, or the like.

[0033] The patient monitor may also include one or more displays capable of displaying trend data for any one or more of the monitored or derived patient parameters. For example, the trend data may be displayed in graph form, may include multiple trend lines, each representing a different monitored or derived patient parameter. Moreover, each trend line may be color-coded to

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facilitate quick comprehension of which trend line represents which measured parameter. However, an artisan will recognize from the disclosure herein a large number of identification techniques including color-coding, identifying text, or the like. Additionally, user input may toggle displayed trend data, may select which parameters to display simultaneously, or the like.

[0034] In an embodiment, the patient monitor includes an audible or visual indication of a type of sensor communicating with the monitor. For example, the patient monitor may provide a particular audio or visual indication, such as a beep, LED activation, graphic activation, text messages, voice messages, or the like, to indicate communication with or connection to an approved sensor, patient cable, combination, or the like. In an embodiment, the indication may change based on the manufacturer, type of sensor recognized or not recognized, type of patient, type of physiological parameters measurable with the attached sensor, or the like. Additional embodiments include an indication of perfusion in the tissue of the measurement site and an indication of the confidence the signal processing has in its output measurements or input signal quality.

[0035] To facilitate an understanding of the disclosure, the remainder of the description references exemplary embodiments illustrated in the drawings. Moreover, in this application, reference is made to many blood parameters. Some references that have common shorthand designations are referenced through such shorthand designations. For example, as used herein, HbCO designates carboxyhemoglobin, HbMet designates methemoglobin, and Hbt designates total hemoglobin. Other shorthand designations such as COHb, MetHb, and tHb are also common in the art for these same constituents. These constituents are generally reported herein in terms of a percentage, often referred to as saturation, relative concentration or fractional saturation. Total hemoglobin is generally reported as a concentration in g/dL. The use of the particular shorthand designators presented in this application does not restrict the term to any particular manner in which the designated constituent is reported.

[0036] **Fig. 1** illustrates a block diagram of an exemplary embodiment of a patient monitoring system **100**. As shown in **Fig. 1**, the system **100** includes a patient monitor **102** comprising a processing board **104** and a host instrument

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108. The processing board **104** communicates with a sensor **106** to receive one or more intensity signal(s) indicative of one or more parameters of tissue of a patient. The processing board **104** also communicates with a host instrument **108** to display determined values calculated using the one or more intensity signals. According to an embodiment, the board **104** comprises processing circuitry arranged on one or more printed circuit boards capable of installation into the monitor **102**, or capable of being distributed as some or all of one or more OEM components for a wide variety of host instruments monitoring a wide variety of patient information. In an embodiment, the processing board **102** comprises a sensor interface **110**, a digital signal processor and signal extractor ("DSP" or "processor") **112**, and an instrument manager **114**. In general, the sensor interface **110** converts digital control signals into analog drive signals capable of driving sensor emitters, and converts composite analog intensity signal(s) from light sensitive detectors into digital data.

[0037] In an embodiment, the sensor interface **110** manages communication with external computing devices. For example, in an embodiment, a multipurpose sensor port (or input/output port) is capable of connecting to the sensor **106** or alternatively connecting to a computing device, such as a personal computer, a PDA, additional monitoring equipment or networks, or the like. When connected to the computing device, the processing board **104** may upload various stored data for, for example, off-line analysis and diagnosis. The stored data may comprise trend data for any one or more of the measured parameter data, plethysmograph waveform data acoustic sound waveform, or the like. Moreover, the processing board **104** may advantageously download from the computing device various upgrades or executable programs, may perform diagnosis on the hardware or software of the monitor **102**. In addition, the processing board **104** may advantageously be used to view and examine patient data, including raw data, at or away from a monitoring site, through data uploads/downloads, or network connections, combinations, or the like, such as for customer support purposes including software maintenance, customer technical support, and the like. Upgradable sensor ports are disclosed in copending U.S. App. No. 10/898,680, filed on July 23, 2004, titled "*Multipurpose Sensor Port*," incorporated by reference herein.

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[0038] As shown in **Fig. 1**, the digital data is output to the DSP **112**. According to an embodiment, the DSP **112** comprises a processing device based on the Super Harvard ARChitecture ("SHARC"), such as those commercially available from Analog Devices. However, a skilled artisan will recognize from the disclosure herein that the DSP **112** can comprise a wide variety of data and/or signal processors capable of executing programs for determining physiological parameters from input data. In particular, the DSP **112** includes program instructions capable of receiving multiple channels of data related to one or more intensity signals representative of the absorption (from transmissive or reflective sensor systems) of a plurality of wavelengths of emitted light by body tissue. In an embodiment, the DSP **112** accepts data related to the absorption of eight (8) wavelengths of light, although an artisan will recognize from the disclosure herein that the data can be related to the absorption of two (2) to sixteen (16) or more wavelengths.

[0039] **Fig. 1** also shows the processing board **104** including the instrument manager **114**. According to an embodiment, the instrument manager **114** may comprise one or more microcontrollers controlling system management, including, for example, communications of calculated parameter data and the like to the host instrument **108**. The instrument manager **114** may also act as a watchdog circuit by, for example, monitoring the activity of the DSP **112** and resetting it when appropriate.

[0040] The sensor **106** may comprise a reusable clip-type sensor, a disposable adhesive-type sensor, a combination sensor having reusable and disposable components, or the like. Moreover, an artisan will recognize from the disclosure herein that the sensor **106** can also comprise mechanical structures, adhesive or other tape structures, Velcro wraps or combination structures specialized for the type of patient, type of monitoring, type of monitor, or the like. In an embodiment, the sensor **106** provides data to the board **104** and vice versa through, for example, a patient cable. An artisan will also recognize from the disclosure herein that such communication can be wireless, over public or private networks or computing systems or devices, or the like.

[0041] As shown in **Fig.1**, the sensor **106** includes a plurality of emitters **116** irradiating the body tissue **118** with differing wavelengths of light,

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and one or more detectors **120** capable of detecting the light after attenuation by the tissue **118**. In an embodiment, the emitters **116** comprise a matrix of eight (8) emission devices mounted on a flexible substrate, the emission devices being capable of emitting eight (8) differing wavelengths of light. In other embodiments, the emitters **116** may comprise twelve (12) or sixteen (16) emitters, although other numbers of emitters are contemplated, including two (2) or more emitters. As shown in **Fig. 1**, the sensor **106** may include other electrical components such as, for example, a memory device **122** comprising an EPROM, EEPROM, ROM, RAM, microcontroller, combinations of the same, or the like. In an embodiment, other sensor components may include a temperature determination device **123** or other mechanisms for, for example, determining real-time emission wavelengths of the emitters **116**.

[0042] The memory **122** may advantageous store some or all of a wide variety data and information, including, for example, information on the type or operation of the sensor **106**; type or identification of sensor buyer or distributor or groups of buyer or distributors, sensor manufacturer information, sensor characteristics including the number of emitting devices, the number of emission wavelengths, data relating to emission centroids, data relating to a change in emission characteristics based on varying temperature, history of the sensor temperature, current, or voltage, emitter specifications, emitter drive requirements, demodulation data, calculation mode data, the parameters for which the sensor is capable of supplying sufficient measurement data (e.g., HpCO, HpMet, HbT, or the like), calibration or parameter coefficient data, software such as scripts, executable code, or the like, sensor electronic elements, whether the sensor is a disposable, reusable, multi-site, partially reusable, partially disposable sensor, whether it is an adhesive or non-adhesive sensor, whether the sensor is a reflectance, transmittance, or transreflectance sensor, whether the sensor is a finger, hand, foot, forehead, or ear sensor, whether the sensor is a stereo sensor or a two-headed sensor, sensor life data indicating whether some or all sensor components have expired and should be replaced, encryption information, keys, indexes to keys or hash functions, or the like, monitor or algorithm upgrade instructions or data, some or all of parameter equations, information about the patient, age, sex, medications, and other

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information that may be useful for the accuracy or alarm settings and sensitivities, trend history, alarm history, or the like. In an embodiment, the monitor may advantageously store data on the memory device, including, for example, measured trending data for any number of parameters for any number of patients, or the like, sensor use or expiration calculations, sensor history, or the like.

[0043] Fig. 1 also shows the patient monitor **102** including the host instrument **108**. In an embodiment, the host instrument **108** communicates with the board **104** to receive signals indicative of the physiological parameter information calculated by the DSP **112**. The host instrument **108** preferably includes one or more display devices **124** capable of displaying indicia representative of the calculated physiological parameters of the tissue **118** at the measurement site. In an embodiment, the host instrument **108** may advantageously comprise a handheld housing capable of displaying one or more of a pulse rate, plethysmograph data, perfusion quality such as a perfusion quality index ("PITM"), signal or measurement quality ("SQ"), values of blood constituents in body tissue, including for example, SpO₂, HbCO, HbMet, Hbt, or the like. In other embodiments, the host instrument **108** is capable of displaying values for one or more of Hbt, Hb, blood glucose, bilirubin, or the like. The host instrument **108** may be capable of storing or displaying historical or trending data related to one or more of the measured values, combinations of the measured values, plethysmograph data, or the like. The host instrument **108** also includes an audio indicator **126** and user input device **128**, such as, for example, a keypad, touch screen, pointing device, voice recognition device, or the like.

[0044] In still additional embodiments, the host instrument **108** includes audio or visual alarms that alert caregivers that one or more physiological parameters are falling below predetermined safe thresholds. The host instrument **108** may include indications of the confidence a caregiver should have in the displayed data. In a further embodiment, the host instrument **108** may advantageously include circuitry capable of determining the expiration or overuse of components of the sensor **106**, including, for example, reusable elements, disposable elements, or combinations of the same.

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[0045] Although described in terms of certain embodiments, other embodiments or combination of embodiments will be apparent to those of ordinary skill in the art from the disclosure herein. For example, the monitor **102** may comprise one or more monitoring systems monitoring parameters, such as, for example, vital signs, blood pressure, ECG or EKG, respiration, glucose, bilirubin, or the like. Such systems may combine other information with intensity-derived information to influence diagnosis or device operation. Moreover, the monitor **102** may advantageously include an audio system, preferably comprising a high quality audio processor and high quality speakers to provide for voiced alarms, messaging, or the like. In an embodiment, the monitor **102** may advantageously include an audio out jack, conventional audio jacks, headphone jacks, or the like, such that any of the display information disclosed herein may be audibilized for a listener. For example, the monitor **102** may include an audible transducer input (such as a microphone, piezoelectric sensor, or the like) for collecting one or more of heart sounds, lung sounds, trachea sounds, or other body sounds and such sounds may be reproduced through the audio system and output from the monitor **102**. Also, wired or wireless communications (such as Bluetooth or WiFi, including IEEE 801.11a, b, or g), mobile communications, combinations of the same, or the like, may be used to transmit the audio output to other audio transducers separate from the monitor **102**.

[0046] For example, patterns or changes in the continuous noninvasive monitoring of intensity-derived information may cause the activation of other vital sign measurement devices, such as, for example, blood pressure cuffs.

[0047] **Fig. 2** illustrates a perspective view of an exemplary handheld noninvasive multi-parameter patient monitor **200**, such as, for example, the patient monitor **102** of **Fig. 2**. Patient monitors **200** exhibiting combinations of many of the features described herein are advantageously commercially available from Masimo under the brand name "Rad 57c." As shown in **Fig. 1**, the monitor **200** includes a patient cable connector **202** capable of mechanical mating with a patient cable to establish communication between the board **104** and the sensor **106**. In an embodiment, the connector **202** comprises a multipurpose cable connector such as that disclosed in the incorporated U.S.

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App. No. 10/898,680, titled "*Multipurpose Sensor Port*," disclosing communication between the board **104** and an external computing device.

[0048] The monitor **202** also comprises a HbCO indicator **204** advantageously providing a visual queue that a HbCO capable sensor is properly connected through the connector **202**. For example, the HbCO indicator **204** may advantageously activate when a sensor is connected that communicates sufficient information to determine HbCO, such as, for example, a sensor capable of emitting sufficient different wavelengths of light, a sensor storing sufficient data on the memory **122**, a sensor having appropriate encryption data or key, combinations of the same, or the like. For example, in an embodiment, the processor **112** may receive information from a memory **122** indicating a number of available LED wavelengths for the attached sensor. Based on the number of wavelengths, or other information stored on the memory **122**, the processor **112** may determine whether an HbCO-ready sensor has been attached to the monitor **200**. An artisan will also recognize from the disclosure herein that the HbCO indicator **204** may advantageously comprise a HbMet indicator, Hbt indicator, or the like, which activates to a predetermined color associated with a parameter, or any color, or deactivates the same, to convey a type of attached sensor. Moreover, the artisan will recognize from the disclosure herein other parameters that may use other sensor components and the monitor **200** may include indicators capable of indicating communication with those types of sensors.

[0049] In an embodiment, the monitor **200** may also audibly indicate the type of sensor connected. For example, the monitor **200** may emit predetermined number or frequency of beeps associated with recognition of a particular sensor, a particular manufacturer, failure to recognize the sensor, or the like. Moreover, the sensor type may be indicative of the componentry, such as, for example, whether the sensor produces sufficient data for the determination of HbCO, HbMet, Hbt and SpO₂, SpO₂ only, SpO₂ and HbMet, any combination of the foregoing or other parameters, or the like. Additionally, the sensor type may be indicative of specific sensors designed for a type of patient, type of patient tissue, or the like. In other embodiments, the monitor **200** may announce the type of connector through speaker **236**.

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[0050] An artisan will also recognize from the disclosure herein that other mechanical (such as keys), electrical, or combination devices may inform the monitor **202** of the type of attached sensor. In an embodiment, the processor **112** also may select to drive less emitters that are currently available, such as, for example, in the presence of low noise and when power consumption is an issue.

[0051] The monitor **202** also comprises a multi-mode display **206** capable of displaying, for example, measurements of SpO₂ and HbCO (or alternatively, HbMet). In an embodiment, the display **206** has insufficient space or display real estate to display the many parameters capable of being measured by the monitor **200**. Thus, the multi-mode display **206** may advantageously cycle through two or more measured parameters in an area common to both parameters even when shifted. In such embodiments, the monitor **200** may also advantageously include parameter indicators **208**, **210**, providing additional visual queues as to which parameter is currently displayed. In an embodiment, the display may also cycle colors, flash rates, or other audio or visual queues providing readily identifiable information as to which measured parameter is displayed. For example, when the multi-mode display **206** displays measured values of SpO₂ that are normal, the numbers may advantageously appear in green, while normal measured values of HbCO may advantageously appear in orange, and normal measured values of HbMet may appear in blue. Moreover, in an embodiment, the display **206** flashes at a predefined rate when searching for saturation and at another predefined rate when a signal quality is below a predetermined threshold.

[0052] The monitor **202** also comprises a HbCO bar **212** where in an embodiment a plurality of LED's activate from a bottom toward a top such that the bar "fills" to a level proportional to the measured value. For example, the bar **212** is lowest when the dangers from carbon monoxide poisoning are the least, and highest when the dangers are the greatest. The bar **212** includes indicia **214** that provide an indication of the severity of carbon monoxide saturation in a patient's blood. As shown in **Fig. 2**, the bar **212** and the indicia **214** continuously indicate the concentration of HbCO in about 5% increments. The indicia **214** indicate a measurement of HbCO saturation percentage between about 0 and

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about 50% with a granularity of about 5%. However, an artisan will also recognize from the disclosure herein a wide variety of ranges and granularities could be used, the indicia **214** could be electronically displayed in order to straightforwardly increase or decrease resolution, or the like. For example, HbCO may advantageously be displayed with greater resolution than \pm about %5 in a lower portion of the scale. For example, an HbCO bar may advantageously include a scale of about <3%, about 6%, about 9%, about 12%, about 15%, about 20%, about 25%, about 30%, about 35%, and about >40%.

[0053] As is known in the art, carbon monoxide in the blood can lead to serious medical issues. For example and depending upon the particular physiology of a patient, about 10% carbon monoxide saturation can lead to headaches, about 20% can lead to throbbing headaches, or dyspnea on exertion, about 30% can lead to impaired judgment, nausea, dizziness and/or vomiting, visual disturbance, or fatigue, about 40% can lead to confusion and syncope, and about 50% and above can lead to comas, seizures, respiratory failure and even death.

[0054] In an embodiment, the bar **212** is the same or similar color as the multi-mode display **206** when displaying HbCO. In other embodiments, the bar **212** is lowest and green when the dangers from carbon monoxide poisoning are the least, and highest and red when the dangers are the greatest. In an embodiment, as HbCO increases, the entire bar **212** may advantageously change color, such as, for example, from green to red, to provide a clear indication of deepening severity of the condition. In other embodiments, the bar **212** may advantageously blink or flash, an audio alarm may beep or provide a continuation or rise in pitch or volume, or the like to alert a caregiver of deepening severity. Moreover, straightforward to complex alarm rules may be implemented to reduce false alarms based on, for example, knowledge of the physiological limitations on the rate of change in HbCO or the like.

[0055] Additionally, the monitor **200** may be capable of storing and outputting historical parameter data, display trend traces or data, or the like. Although the foregoing bar **212** has been described in terms of certain preferred embodiments, other embodiments will be apparent to those of ordinary skill in the art from the disclosure herein.

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[0056] Fig. 2 also shows the monitor **200** including a pulse display **216** displaying measured pulse rate in beats per minute (“BPM”). In an embodiment, the display **212** flashes when searching for a pulse. The pulse display **216** advantageously displays measured pulse rates from about zero (0) to about two hundred and forty (240) BPM. Moreover, when the measured pulse rates are considered normal, the pulse display **216** is advantageously green. Similar to other displays associated with the monitor **200**, the pulse display **216** may employ a variety of color changes, audio alarms, or combinations of the same to indicate measured BPM below predetermined safe thresholds. In an embodiment, the pulse rate display **216** displays the measured pulse rate during the display of SpO₂ and displays message data during the display of other parameters. For example, during the display of HbCO, the display **216** may advantageously display the term “CO.” In an embodiment, the display of the message data may be in the same or similar color as the other displays. For example, in an embodiment, the multi-mode display **206**, the bar **212**, and the pulse display **216** may all display data or messages in orange when the multi-mode display **206** displays measured HbCO values.

[0057] Fig. 2 also illustrates the monitor **200** comprising user input keys **218**, including a HbCO button **220**, mode/enter button **222**, next button **224**, power on/off button **226**, up/down button **228**, and alarm silence button **230**. In an embodiment, activation of the HbCO button **220** toggles the measured value displayed in the multi-mode display **206**. For example, activation of the HbCO button **220** toggles the multi-mode display **206** from displaying measured values of SpO₂ to HbCO for about ten (10) seconds. Activation of the mode/enter button **222** or the next button **224** during the ten (10) second period returns the multi-mode display **206** back to SpO₂. A skilled artisan will also recognize that activation of the HbCO button **220** may advantageously toggle through a plurality of measured values, and that such values may be displayed for short segments and then return to SpO₂, may remain displayed until further activation of the button **220**, or the like.

[0058] Activation of the mode/enter button **222** cycles through various setup menus allowing a caregiver to select or activate certain entries within the menu setup system, including alarm threshold customizations, or the like.

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Activation of the next button **224** can move through setup options within the menu setup system and in an embodiment is not active during normal patient monitoring. For example, a caregiver may activate the mode/enter button **222** and the next button **224** to specify high and low alarm thresholds for one or more of the measured parameters, to specify device sensitivity, trend settings, display customizations, color code parameters, or the like. In an embodiment, the high alarm setting for SpO₂ can range from about two percent (2%) to about one hundred percent (100%) with a granularity of about one percent (1%). The low alarm setting for SpO₂ can range from about one percent (1%) to about one hundred percent (100%) with a granularity of about one percent (1%). Moreover, the high alarm setting for pulse rate can range from about thirty (30) BPM to about two hundred and forty (240) BPM with a granularity of about five (5) BPM. The low alarm setting for pulse rate can range from about twenty five (25) BPM to about two hundred and thirty five (235) BPM with a granularity of about five (5) BPM. Other high and low ranges for other measured parameters will be apparent to one of ordinary skill in the art from the disclosure herein.

[0059] In a further embodiment, a caregiver may activate the mode/enter button **222** and the next button **224** to specify device sensitivity, such as, for example, device averaging times, probe off detection, whether to enable fast saturation calculations, or the like. Various embodiments of fast saturation calculations are disclosed in U.S. Pat. App. Ser. No. 10/213,270, filed August 5, 2002, titled "*Variable Indication Estimator*" and incorporated by reference herein. Using the menus, a caregiver may also advantageously enter appropriate information governing trend collection on one or more of the measured parameters, input signals, or the like.

[0060] **Fig. 2** also shows the power on/off button **226**. Activation of the power on/off button **226** activates and deactivates the monitor **200**. In an embodiment, press-and-hold activation for about two (2) seconds shuts the monitor **200** off. In an additional embodiment, activation of the on/off button **226** advantageously initiates detection of a type of attached sensor. For example, activation of the on/off button **226** may advantageously cause the monitor **200** to read information from a memory on an attached sensor and determine whether

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sufficient wavelengths exist on the sensor to determine one or more the physiological parameters discussed in the foregoing.

[0061] An artisan will recognize from the disclosure herein that the on/off button **226** may advantageously cause an electronic determination of whether to operate in at powers consisted with the U.S. (60 Hz) or another nationality (50 Hz). In an embodiment, such automatic determination and switching is removed from the monitor **200** in order to reduce a likelihood of problematic interfering crosstalk caused by such power switching devices.

[0062] Activation of the up/down button **228** may advantageously adjust the volume of the pulse beep tone. Additionally, activation of the up/down button **228** within the menu setup system, causes the selection of values with various menu options.

[0063] Moreover, activation of the alarm silence button **230** temporarily silences audio alarms for a predetermined period, such as, for example, about one hundred and twenty (120) seconds. A second activation of the alarm silence button **230** mutes (suspends) the alarm indefinitely, while a third activation returns the monitor **200** to standard alarm monitoring. **Fig. 2** also shows the alarm silence button **230** includes an alarm silenced indicator **232**. The alarm silenced indicator **232** may advantageously flash to indicate one or more alarms are temporarily silenced, may illuminate solid to indicate the alarms have been muted, or the like. Moreover, an artisan will recognize from the disclosure herein a wide variety of alarm silencing methodologies.

[0064] The monitor **202** also includes a battery level indicator **234** indicating remaining battery life. In the illustrated embodiment, four LED's indicate the status of the battery by incrementally deactivating to indicate proportionally decreasing battery life. In an embodiment, the four LED's may also change color as the battery charge decreases, and the final LED may begin to flash to indicate that the caregiver should replace the batteries.

[0065] **Fig. 2** also shows the monitor **202** including an audio transducer or speaker **236**. The speaker **236** advantageously provides audible indications of alarm conditions, pulse tone and feedback for key-presses, or the like. Moreover, the monitor **202** includes a low signal quality indicator ("SQ" or "SIQTM") **238**. The signal IQ indicator **238** activates to inform a caregiver that a

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measured value of the quality of the incoming signal is below predetermined threshold values. For example, in an embodiment, the measured value for signal IQ is at least partially based on an evaluation of the plethysmograph data's correspondence to predetermined models or characteristics of physiological signals. In an embodiment, the signal IQ indicator **238** output may be associated with the displayed parameter. For example, the output may be associated with one threshold for the display of SpO₂ and another for the display of other parameter data.

[0066] The monitor **202** also comprises a perfusion quality index ("PITM") bar **240** (which quantifies the measure of perfusion of the patient) where in an embodiment a plurality of LED's activate from a bottom toward a top such that the bar "fills" to a level proportional to the measured value. In one embodiment, the PITM bar **240** shows a static value of perfusion for a given time period, such as, for example, one or more pulses. In another embodiment, or functional setting, the PITM bar **240** may advantageously pulse with a pulse rate, may hold the last reading and optionally fade until the next reading, may indicate historical readings through colors or fades, or the like. Additionally, the PITM bar **240** may advantageously change colors, flash, increasingly flash, or the like to indicate worsening measured values of perfusion.

[0067] The PITM bar **240** can be used to simply indicate inappropriate occlusion due, for example, to improper attachment of the sensor **106**. The PITM bar **240** can also be used as a diagnostic tool during low perfusion for the accurate prediction of illness severity, especially in neonates. Moreover, the rate of change in the PITM bar **240** can be indicative of blood loss, sleep arousal, sever hypertension, pain management, the presence or absence of drugs, or the like. According to one embodiment, the PITM bar **240** values may comprise a measurement of the signal strength of the arterial pulse as a percentage of the total signal received. For example, in one preferred embodiment, the alternating portion of at least one intensity signal from the sensor **106** may advantageously be divided by the static portion of the signal. For example, an infrared intensity signal may advantageously be used as it is less subjective to noise.

[0068] In an embodiment, a measurement below about 1.25% may indicate medical situations in need of caregiver attention, specifically in

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monitored neonates. Because of the relevance of about 1.25%, the PITM bar **240** may advantageously include level indicia **242** where the indicia **242** swap sides of the PITM bar **240**, thus highlighting any readings below about that threshold. Moreover, behavior of the PITM bar **240**, as discussed above, may advantageously draw attention to monitored values below such a threshold.

[0069] As discussed above, the monitor **200** may include output functionality that outputs, for example, trend perfusion data, such that a caregiver can monitor measured values of perfusion over time. Alternatively or additionally, the monitor **200** may display historical trace data on an appropriate display indicating the measured values of perfusion over time. In an embodiment, the trend data is uploaded to an external computing device through, for example, the multipurpose sensor connector **202** or other input output systems such as USB, serial or parallel ports or the like.

[0070] The monitor **200** also includes an alarm indicator **244** capable of providing visual queues of the status of one or more of the measured parameters. For example, the alarm indicator **244** may advantageously be green when all of the measured parameters are within normal conditions, may gradually fade to red, may flash, increasing flash, or the like, as one or more of the measured values approaches or passes predetermined thresholds. In an embodiment, the alarm indicator **244** activates when any parameter falls below an associated threshold, thereby advantageously informing a caregiver that perhaps a nondisplayed parameters is at an alarm condition. In another embodiment, the alarm indicator **244** may indicate the status of the parameter displayed on the multi-mode display **206**. In an embodiment, the speaker **236** may sound in conjunction with and/or in addition to the indicator **244**. Moreover, in an embodiment, an alarming parameter may automatically be displayed, may be emphasized, flashed, colored, combinations of the same or the like to draw a user's attention to the alarming parameter.

[0071] Although the foregoing invention has been described in terms of certain preferred embodiments, other embodiments will be apparent to those of ordinary skill in the art from the disclosure herein.

[0072] **Fig. 3** illustrates an exemplary display of the patient monitor **200**. As shown in **Fig. 3**, the display includes the multi-mode display **206**, the

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pulse rate display **216**, parameter indicators **208**, **210**, the HbCO bar **212** and indicator **204**, the PITM bar **240**, and the alarm indicator **244**. In an embodiment, the multi-mode display **206** and the pulse rate display **216** each comprise a plurality of seven segment displays **302** capable of displaying alpha-numeric information. As disclosed in the foregoing, the exemplary display may advantageously include color-coded parameter displays. Moreover, the exemplary display may include color progressions, flashing, flashing progressions, audible alarms, audible progressions, or the like, indicating worsening measured values of physiological data. In addition, in an embodiment, some or all of the displays may flash at a first rate to indicate attempts to acquire data when actual measured values are unavailable. Moreover, some or all of the display may flash at a second rate to indicate low signal quality where confidence is decreasing that the measured values reflect actual physiological conditions.

[0073] **Fig. 4** illustrates the display of **Fig. 3** showing measured values of SpO₂, BPM, perfusion, and type of sensor, according to an exemplary embodiment of the patient monitor of **Fig. 1**. As shown in **Fig. 4**, the multi-mode display **206** is displaying a percentage value of SpO₂, and the pulse rate display **216** is displaying a pulse rate in beats per minute. Accordingly, the parameter indicator **210** is activated to confirm the display of measured values of SpO₂. As disclosed in the foregoing, in an embodiment, the multi-mode display **206** is red, indicating blood oxygen measurements while the pulse rate display **216** is green, indicating normal values of a patient's pulse.

[0074] **Fig. 4** also shows the PITM bar **240** almost fully activated, representing good perfusion. In addition, the HbCO indicator **204** is showing communication with a sensor producing insufficient data to determine measured values of additional parameters, such as, HbCO. In an embodiment, such sensors may comprise sensors capable of emitting light at about two (2) different wavelengths, may comprise sensors with insufficient data stored on a memory associated therewith, or the like.

[0075] **Fig. 5** illustrates the display of **Fig. 3** showing measured values of HbCO, perfusion, and type of sensor, according to an exemplary embodiment of the patient monitor of **Fig. 1**. As shown in **Fig. 5**, the multi-mode display **206**

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is displaying a percentage value of HbCO, and the pulse rate display **216** is displaying an appropriate message indicating the HbCO measurement, such as, for example, "CO". Also, the multi-mode display **206** has shifted the data to the left to quickly and efficiently indicate that the displayed parameter is other than SpO₂. Accordingly, the parameter indicator **208** is also activated to confirm the display of measured values of HbCO. As disclosed in the foregoing, in an embodiment, the multi-mode display **206** and pulse rate display message **216** are orange.

[0076] **Fig. 5** also shows the PITM bar **240** almost fully activated, representing good perfusion. In addition, the activation of the HbCO indicator **204** represents communication with a sensor capable of producing sufficient data to determine measured values of HbCO. In an embodiment, such sensors may comprise sensors capable of emitting light at about eight (8) or more different wavelengths; however, such sensors may comprise about two (2) or more different wavelengths. Moreover, such sensors may have appropriate data stored on a memory associated therewith, or the like. **Fig. 5** also shows the HbCO measurement being about 20% (as illustrated on the HbCO bar **212** and multi-mode display **206**) thereby indicating a potentially dangerous situation that if exacerbated, will become quite problematic. Therefore, the alarm indicator **244** is also activated, and in some embodiments, the speaker **236** as well.

[0077] **Fig. 6** illustrates the display of **Fig. 3** showing measured values of SpO₂, HbCO, BPM, perfusion, and type of sensor, according to an exemplary embodiment of the patient monitor of **Fig. 1**. In contrast to **Fig. 4**, **Fig. 6** shows that the monitor **200** is communicating with a sensor capable of producing sufficient data to determine measured values of HbCO, even though the displayed values are that of SpO₂ and BPM. Thus, **Fig. 6** shows the activation of the HbCO indicator **204**, and the continuous monitoring of HbCO by the HbCO bar **212**. **Fig. 6** also shows a high value of HbCO, and therefore, the indication of an alarm condition by activation of the alarm indicator **244**. In an embodiment, upon determination of an alarm condition on a nondisplayed parameter, the monitor **200** may advantageously provide an alarm indication through speaker and alarm indicator activation, automatic toggle to the nondisplayed parameter on the multi-mode display **206** for a defined or undefined time, or the like.

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[0078] **Fig. 7** illustrates a top elevation view of an exemplary handheld noninvasive multi-parameter patient monitor **700** capable of displaying at least HbCO and HbMet, such as, for example, the patient monitor of **Fig. 1**. Patient monitors exhibiting combinations of many of the features described herein are advantageously commercially available from Masimo under the brand name “Rad 57cm.” As shown in **Fig. 7**, the monitor **700** comprises a monitor similar to monitor **200** disclosed with reference to **Fig. 2**. Moreover, monitor **700** further includes a multi-mode display **706** capable of displaying, for example, measurements of HbMet and BPM. In an embodiment, the display **706** has insufficient space or display real estate to display the many parameters capable of being measured by the monitor **700**. Thus, the multi-mode display **706** may advantageously cycle through two or more measured parameters. In such embodiments, the monitor **700** may also advantageously include parameter indicators **708**, **710**, providing additional visual queues as to which parameter is currently displayed. In an embodiment, the display **706** may also cycle colors, flash rates, or other audio or visual queues providing readily identifiable information as to which measured parameter is displayed. For example, when the multi-mode display **706** displays measured values of BPM that are normal, the numbers may advantageously appear in green, while normal measured values of HbMet may appear in blue. Moreover, in an embodiment, the display **706** may flash at a predefined rate when searching for saturation and at another predefined rate when a signal quality is below a predetermined threshold.

[0079] **Fig. 7** also illustrates the monitor **700** comprising user input keys **718**, including an HbCO/HbMet button **220**. In an embodiment, activation of the HbCO/HbMet button **720** toggles the measured value displayed in the multi-mode display **706**. For example, activation of the HbCO/HbMet button **720** toggles the multi-mode display **206** from displaying measured values of SpO₂ and BPM, to HbCO and HbMet for about ten (10) seconds. Activation of the mode/enter button **222** or the next button **224** during the ten (10) second period returns the multi-mode display **706** back to SpO₂ and BPM. A skilled artisan will also recognize that activation of the HbCO/HbMet button **720** may advantageously toggle through a plurality of measured values, and that such

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values may be displayed for short segments and then return to SpO₂ and BPM, may remain displayed until further activation of the button **720**, or the like.

[0080] The monitor **700** also comprises a coarser indication of HbMet through an HbMet bar **740**. In an embodiment, a plurality of LED's activate from a bottom toward a top such that the bar "fills" to a level proportional to the measured value, with increments at about 0.5%, about 1%, about 2%, about 3%, about 4%, about 5%, about 7.5%, about 10%, about 15% and greater than about 20%, although an artisan will recognize from the disclosure herein other useful delineations. Additionally, the HbMet bar **740** may advantageously change colors, flash, increasingly flash, or the like to indicate worsening measured values of perfusion.

[0081] Although disclosed with reference to the HbMet bar **740**, and artisan will recognize from the disclosure herein other coarse or even gross indications of HbMet, or any measured parameter. For example, a single LED may advantageously show green, yellow, and red, to indicate worsening coarse values of HbMet. Alternatively, a single LED may simply light to indicate an alarm or approaching alarm condition.

[0082] **Fig. 8** illustrates an exemplary display of the patient monitor **700** of **Fig. 7**. As shown in **Fig. 8**, the display includes the multi-mode displays **206**, **706**, parameter indicators **208**, **210**, **708**, **710**, the HbCO bar **212** and indicator **204**, the HbMet bar **740**, and the alarm indicator **244**. In an embodiment, the multi-mode display **706** is similar to multi-mode display **206**, comprising a plurality of seven segment displays **302** capable of displaying alpha-numeric information, and capable of altering its display characteristics or aspects in a wide variety of configurations discussed with reference to the display **206**.

[0083] **Fig. 9** illustrates the display of **Fig. 8** showing measured values of SpO₂, BPM, HbCO, HbMet, and type of sensor according to an exemplary embodiment of the patient monitor of **Fig. 1**. **Fig. 9** also shows the HbMet bar **740** near the bottom and corresponding to about 1%, representing acceptable HbMet, while the HbCO bar **212** hovers at a dangerous near 20%. In addition, the HbCO indicator **204** is showing communication with a sensor producing sufficient data to determine measured values of additional parameters, such as, HbMet, HbCO or the like. In an embodiment, such sensors may comprise

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sensors capable of emitting light of more than two (2) different wavelengths, preferably more than four (4) different wavelengths, and more preferably eight (8) or more different wavelengths.

[0084] **Fig. 10** illustrates the display of **Fig. 8** showing measured values of HbCO, HbMet, and type of sensor according to an exemplary embodiment of the patient monitor of **Fig. 1**. As shown in **Fig. 10**, the multi-mode display **706** is displaying a percentage value of HbMet that is shifted using the parameter indicator **708**. The data has been advantageously shifted to the left to quickly and efficiently indicate that the displayed parameter is other than BPM. Accordingly, the parameter indicator **708** is also activated to confirm the display of measured values of HbMet. As disclosed in the foregoing, in an embodiment, the multi-mode display **706** is blue.

[0085] **Fig. 10** also shows the HbMet bar **740** nearly empty, representing acceptable HbMet. In addition, the activation of the HbCO indicator **204** represents communication with a sensor capable of producing sufficient data to determine measured values of HbCO. In an embodiment, such sensors may have appropriate data stored on a memory associated therewith, or the like. **Fig. 10** also shows the HbCO measurement being about 20% (as illustrated on the HbCO bar **212** and multi-mode display **206**) thereby indicating a potentially dangerous situation that if exacerbated, will become quite problematic. Therefore, the alarm indicator **244** is also activated, and in some embodiments, the speaker **236** as well.

[0086] **Fig. 11A** illustrates a perspective view of an exemplary noninvasive multi-parameter patient monitor **1100**, such as, for example, the patient monitor of **Fig. 1**. Moreover, **Figs. 11B – 11E** illustrate exemplary display screens of the patient monitor of **Fig. 11A**. As shown in **Figs. 11A – 11B**, an embodiment of the monitor **1100** includes a display **1101** showing a plurality of parameter data. For example, the display may advantageously comprise a CRT or an LCD display including circuitry similar to that available on oximeters commercially available from Masimo Corporation of Irvine, California sold under the name RadicalTM, and disclosed in the U.S. patents referenced above and incorporated above. However, an artisan will recognize from the disclosure herein many commercially available display components capable of displaying

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multiple parameter data along with the ability to display graphical data such as plethysmographs, trend traces, and the like.

[0087] In an embodiment, the display includes a measured value of SpO₂ **1102**, a measured value of pulse rate **1104** in BPM, a plethysmograph **1106**, a measured value of HbCO **1108**, a measured value of HbMet **1110**, a measured value of a perfusion quality **1112**, a measured value of Hbt **1114**, and a derived value of fractional saturation "SpaO₂" **116**. In an embodiment, SpaO₂ comprises HbO₂ expressed as a percentage of the four main hemoglobin species, i.e., HbO₂, Hb, HbCO, and HbMet.

[0088] In an embodiment, one or more of the foregoing parameter includes trending or prediction indicators **1118** showing the current trend or prediction for that corresponding parameter. In an embodiment, the indicators **1118** may advantageously comprise an up arrow, a down arrow, and a hyphen bar to indicate up trending/prediction, down trending/prediction, or neutral trending/prediction.

[0089] **Fig. 11C** illustrates an exemplary display screen showing trend graph **1140** including trend line **1142** for HbMet. In an embodiment, the trend line **1142** may be advantageously colored for quick straightforward recognition of the trending parameter, may be associated with any one or more of the foregoing alarm attributes, may include trending lines for other parameters, or the like. The display screen also shows trending directional indicators **1142**, **1144** for many of the displayed physiological parameters. In an embodiment, the directional indicators **1142**, **1144** may advantageously comprises arrows showing the recent trend, predicted trend, user-customizable trend, combinations thereof, or the like for the associated parameters. In an embodiment, the directional indicators **1142**, **1144** comprises an up arrow indicating a rising trend/predicted trend, a middle bar indicating a somewhat stable trend/predicted trend, and a down arrow indicating a lowering trend/predicted trend. An artisan will recognize a wide variety of other directional indicators **1142**, **1144** from the disclosure herein.

[0090] **Fig. 11D** shows an exemplary display screen in vertical format. Such vertical format could be user actuated or based on a gravity switch. **Figs. 11E – 11F** illustrate additional displays of various physiological parameters similar to those discussed in the foregoing. being As shown in **Fig. 11G**, the

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display includes a measured value of SpO₂ **1162**, a measured value of pulse rate **1164** in BPM, a plethysmograph **1166**, a HbCO bar **1168**, and a HbMet bar **1170**. In an embodiment, the HbCO bar **1168** and HbMet bar **1170** may advantageously behave the same or similarly to the HbCO bar **212** and HbMet bar **712**. Moreover, similar bars may advantageously display any of the physiological parameters discussed herein using display indicia appropriate to that parameter. For example, a SpO₂ or SpaO₂ bar may advantageously range from about 0% to about 100%, and more preferably range from about 50% to about 100%, while a Hbt bar may advantageously range from about 0 to about 30.

[0091] Moreover, similar to the disclosure above, the measured value of SpO₂ **1162** may advantageously toggle to measured values of HbCO, HbMet, Hbt, or the like based on, for example, actuation of user input keys, or the like.

[0092] In addition to the foregoing, the display may also include graphical data showing one or more color-coded or other identifying indicia for traces of trend data. Moreover, other graphical presentations may advantageously provide readily identifiable indications of monitored parameters or combinations of monitored parameters of the patient. For example, in an embodiment, the display includes a SpaO₂ graph **1172**. The SpaO₂ graph **1172** plots SpO₂ as a function of other blood analytes (1-SpaO₂), where SpaO₂ comprises HbO₂ expressed as a percentage of the four main hemoglobin species, i.e., HbO₂, Hb, HbCO, and HbMet. Thus, as shown in **Fig. 11C**, as the slope of the displayed line or arrow increases, the caregiver can readily note that the majority of hemoglobin carriers are being used to carry oxygen, and not, for example, harmful carbon monoxide. On the other hand, as the slope decreases, the caregiver can readily and advantageously note that the number of hemoglobin species available to carry oxygen is decreasing, regardless of the current value of SpO₂. Moreover, the length of the arrow or line also provides an indication of wellness, e.g., the higher the line the more oxygen saturation, the lower the line, the more likely there may be desaturation event, or the like.

[0093] Thus, the SpaO₂ graph **1172** provides the caregiver with the ability to recognize that even though the measured value of SpO₂ may be within acceptable ranges, there are potentially an unacceptable number of hemoglobin

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carriers unavailable for carrying oxygen, and that other potential problems may exist, such as, for example, harmful carbon monoxide levels, or the like. In an embodiment, various alarm conditions may cause the graph **1172** to change color, flash, or any combination of alarm indications discussed in the forgoing. Moreover, **Fig. 111** illustrates yet an additional display of the foregoing parameters.

[0094] An embodiment may also include the monitor **1100** advantageously defining regions of wellness/severity of the monitored patient. For example, because the graph **1172** comprises two dimensions, the monitor **1100** may advantageously define regions where the patient's measured physiological parameters are considered acceptable, regions where the patient is considered at risk, regions where the patient is critical, and the like. For example, one region of acceptability may include a high SpO_2 and a low 1-SpaO_2 , another region of risk may include a high SpO_2 and a high 1-SpaO_2 , and another critical region may include a low SpO_2 and a high 1-SpaO_2 . Moreover, an artisan will recognize from the disclosure herein that different parameters may also be combined to provide readily identifiable indications of patient wellness.

[0095] In addition to or as an alternative to the two dimensional SpaO_2 graph **1172**, the monitor **1100** may also include a three dimensional graph, such as, for example, extending the graph **1172** along the variable of time. In this embodiment, the forgoing regions advantageously become three dimensional surfaces of wellness. Moreover, trend data may also be advantageously added to the surface to provide a history of when particular monitored parameters dipped in and out of various surfaces of wellness, risk, criticality, or the like. Such trend data could be color-coded, text identified, or the like. An artisan will also recognize that such surfaces may be dynamic. For example, measurements of $\text{HbCO} > \text{about } 5$ may dictate that trend data showing $\text{SpO}_2 < \text{about } 90\%$ should be considered critical; however, measurements of $\text{HbCO} < \text{about } 5$ may dictate only $\text{SpO}_2 < \text{about } 85\%$ would be critical. Again, an artisan will recognize from the disclosure herein other parameter combinations to create a wide variety of wellness/critical regions or surfaces that provide readily available visual or audio indications of patient well being, trigger specific alarms, or the like.

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[0096] Moreover, the monitor **1100** may advantageously employ enlargement or reorganization of parameter data based on, for example, the severity of the measurement. For example, the monitor **1100** may display values for HbCO in a small portion of the screen or in the background, and when HbCO begins to approach abnormal levels, the small portion may advantageously grown as severity increases, even in some embodiments to dominate the display. Such visual alarming can be combined with audio alarms such as announcements, alarms, rising frequencies, or the like, and other visual alarms such as flashing, coloration, or the like to assist a caregiver in noticing the increasing severity of a monitored parameter. In an embodiment, a location of the display of an alarming value is changed to be displayed in a larger display area, such as **1102**, so as to be readily noticeable and its display values readily ascertainable.

[0097] Although the foregoing invention has been described in terms of certain preferred embodiments, other embodiments will be apparent to those of ordinary skill in the art from the disclosure herein. For example, the monitor **100** may advantageously be adapted to monitor or be included in a monitor capable of measuring physiological parameters other than those determined through absorption spectroscopy, such as, for example, blood pressure, ECG, EKG, respiratory rates, volumes, inputs for blood pressure sensors, acoustical sensors, and the like. Moreover, the monitor **100** may be adapted for wireless communication to and from the sensor **106**, and/or to and from other monitoring devices, such as, for example, multi-parameter or legacy monitoring devices.

[0098] Also, other combinations, omissions, substitutions and modifications will be apparent to the skilled artisan in view of the disclosure herein. Accordingly, the present invention is not intended to be limited by the reaction of the preferred embodiments, but is to be defined by reference to the appended claims.

[0099] Additionally, all publications, patents, and patent applications mentioned in this specification are herein incorporated by reference to the same extent as if each individual publication, patent, or patent application was specifically and individually indicated to be incorporated by reference.

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WHAT IS CLAIMED IS:

1. A physiological monitor that determines a type of noninvasive optical sensor attached, the physiological monitor comprising a device capable of determining a number of light emitting sources that are to be activated during operation of a noninvasive optical sensor.

2. The physiological monitor of Claim 1, wherein the device comprises a processor capable of receiving information from an information element associated with one or more of a cable and the noninvasive optical sensor, the information being usable to determine the number of light emitting sources available to the monitor.

3. The physiological monitor of Claim 1, wherein the device comprises a presence or absence of a mechanical key associated with one of a cable and the noninvasive optical sensor.

4. A physiological monitoring system comprising:
a first sensor including a first number of light emitting sources usable to determine measurements of at least one blood parameter;
a second sensor including a second number of light emitting sources usable to determine measurements of at least one blood parameter, wherein the first number is different than the second number;
and

a patient monitor including a device which determines which of the first and second sensors is attached to the patient monitor.

5. The physiological monitor of Claim 4, comprising an indicator responsive to the device to inform a user which of the first and second sensors is attached to the patient monitor.

6. The physiological monitor of Claim 5, wherein the indicator activates to inform the user which of the first and second sensors is attached when the physiological monitor is powered on.

7. The physiological monitor of Claim 5, wherein the indicator activates to inform the user which of the first and second sensors is attached when one of the first and second sensor is attached to the physiological monitor.

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8. The physiological monitor of Claim 5, wherein the indicator is continuously active to inform the user.

9. The physiological monitor of Claim 5, wherein the indicator comprises a visual indicator.

10. The physiological monitor of Claim 9, wherein the visual indicator comprises a color.

11. The physiological monitor of Claim 9, wherein the visual indicator comprises an LED.

12. The physiological monitor of Claim 11, wherein the LED changes color based on which of the first and second sensors is attached.

13. The physiological monitor of Claim 12, wherein the LED color comprises red when the first sensor is attached and another color when another sensor is attached.

14. The physiological monitor of Claim 5, wherein the indicator comprises an audible indicator.

15. The physiological monitor of Claim 14, wherein the audible indicator comprises one or more tones.

16. The physiological monitor of Claim 15, wherein the audible indicator emits a first tone when the first sensor is attached and a different second tone when the second sensor is attached.

17. The physiological monitor of Claim 14, wherein the audible indicator perceptibly changes emission sound based on which of the first and second sensor is attached.

18. The physiological monitor of Claim 4, wherein the first and second blood parameters comprise the same blood parameter.

19. The physiological monitor of Claim 4, wherein the first and second blood parameters comprise different blood parameters.

20. The physiological monitor of Claim 4, wherein the device comprises a processor.

21. The physiological monitor of Claim 20, wherein the processor communicates with a memory device to determine which of the first and second sensors is attached to the patient monitor.

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22. The physiological monitor of Claim 21, wherein the memory device comprises a first memory device associated with a first sensor and the memory device comprises a second memory device associated with the second sensor.

23. A method of informing a user of a patient monitor about one of a type of sensor communicating with the patient monitor and a type of physiological parameter determinable using the sensor communicating with the patient monitor, the method comprising:

receiving information from an information element associated with one of an optical sensor and a communication cable between a patient monitor and an optical sensor;

determining a number of wavelengths emitted by the optical sensor from the information; and

activating an indicator based on the number wavelengths emitted by the optical sensor.

24. The method of Claim 23, wherein the indicator comprises a display of data determined using signals from the optical sensor.

25. The method of Claim 23, wherein the indicator comprises a visual indicator.

26. The method of Claim 25, wherein the visual indicator comprises a color.

27. The method of Claim 25, wherein the visual indicator comprises an LED.

28. The method of Claim 27, wherein the LED changes color based on which of the first and second sensors is attached.

29. The method of Claim 27, wherein the LED color comprises red when the first sensor is attached and another color when another sensor is attached.

30. The method of Claim 23, wherein the indicator comprises an audible indicator.

31. The method of Claim 30, wherein the audible indicator comprises one or more tones.

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32. The method of Claim 30, wherein the audible indicator emits a first tone when the first sensor is attached and a different second tone when the second sensor is attached.

33. A physiological parameter monitor capable of improving performance by activating more light emission sources of an optical sensor, the monitor comprising a processor capable of determining a number of light emission sources available for activation on an attached sensor and capable of activating two of the plurality of light emission sources and capable of activating more than two of the plurality of light emission sources.

34. The monitor of Claim 33, wherein the processor activates two of the plurality of light emission sources to measure a first physiological parameter.

35. The monitor of Claim 34, wherein the processor activates more than two of the plurality of light emission sources to measure a second physiological parameter.

36. The monitor of Claim 34, wherein the processor activates more than two of the plurality of light emission sources to more accurately measure the first physiological parameter.

37. The monitor of Claim 33, wherein the processor activates more than two of the plurality of light emission sources to measure a second physiological parameter.

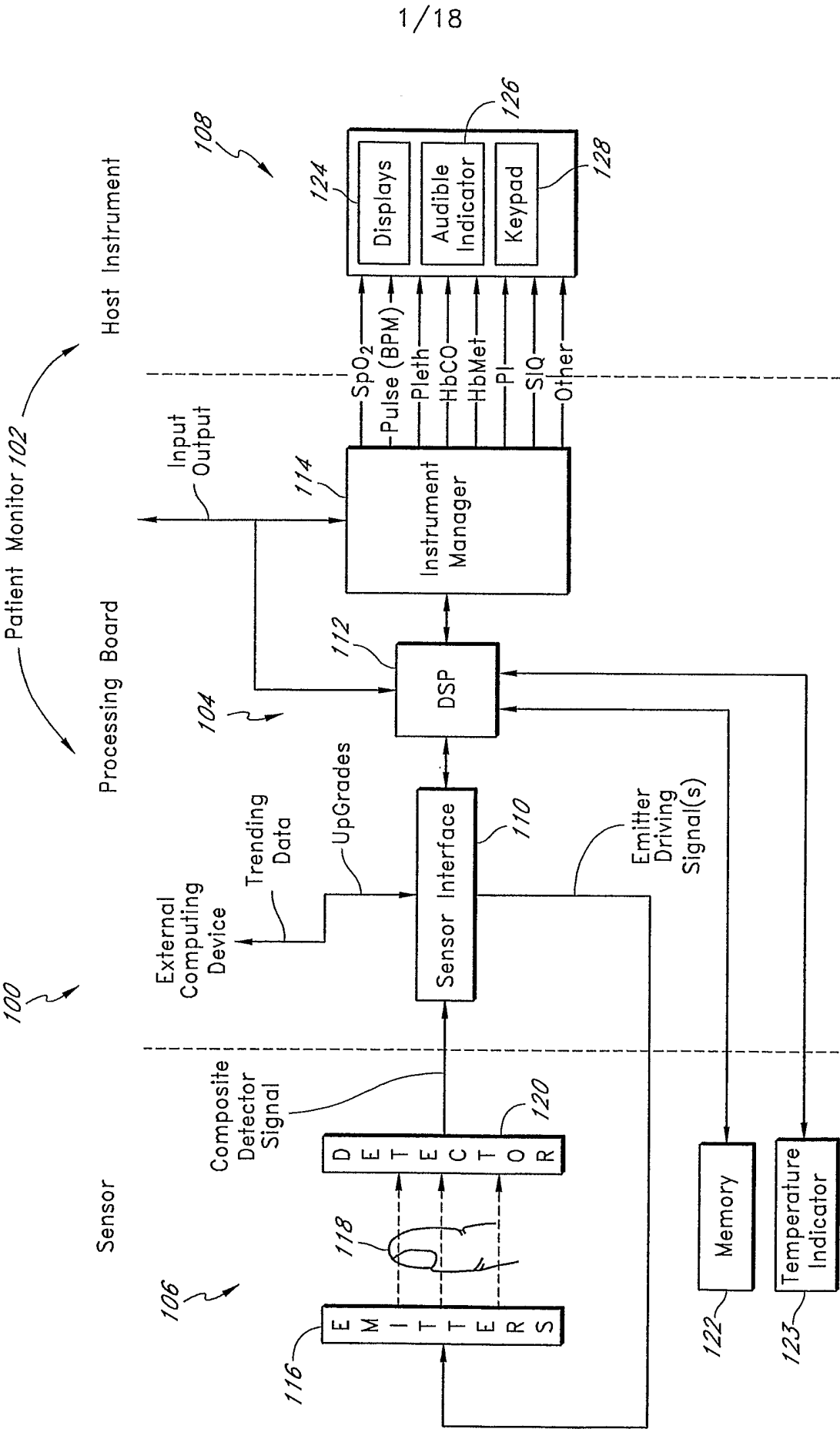


FIG. 1

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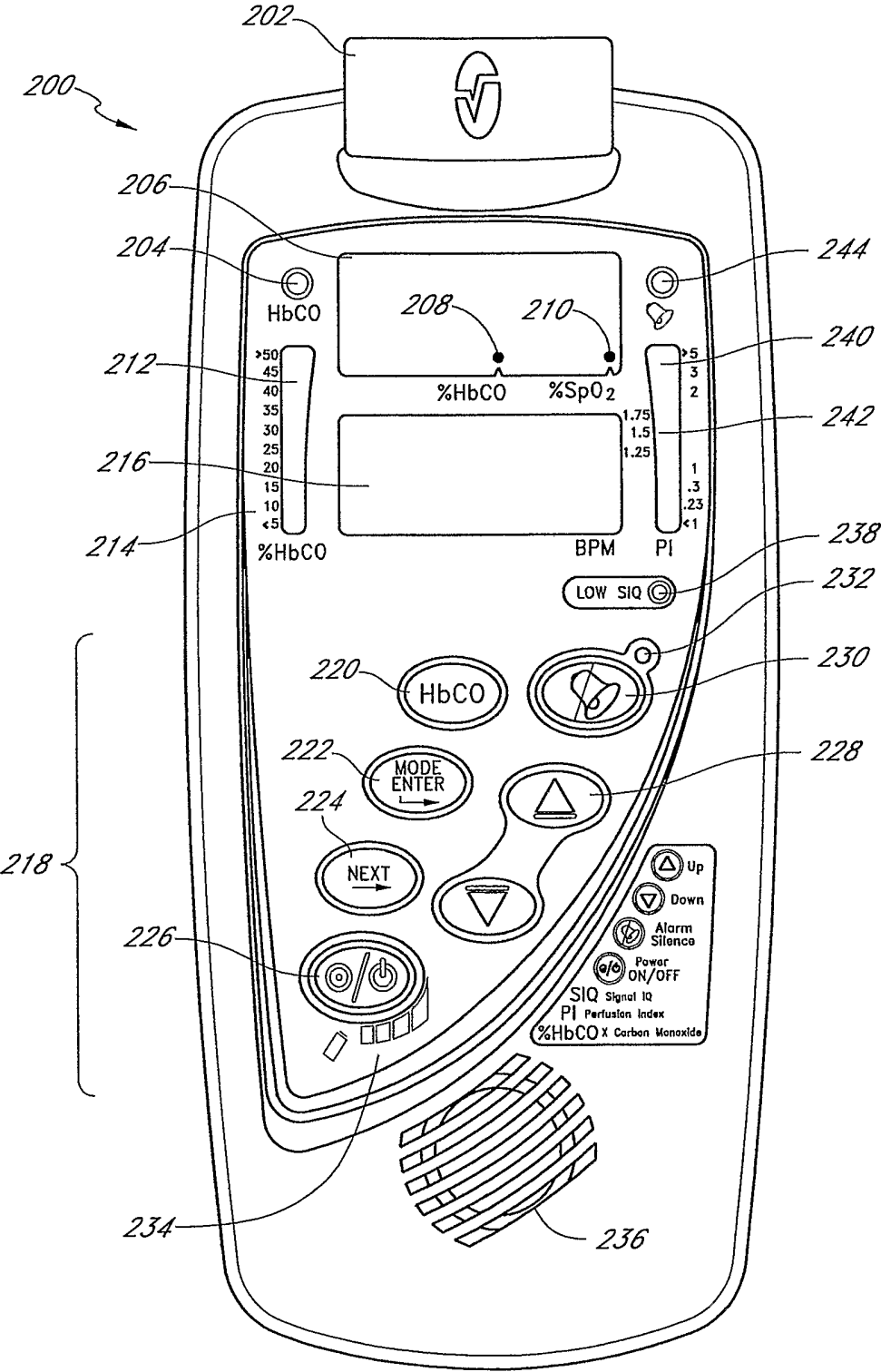


FIG. 2

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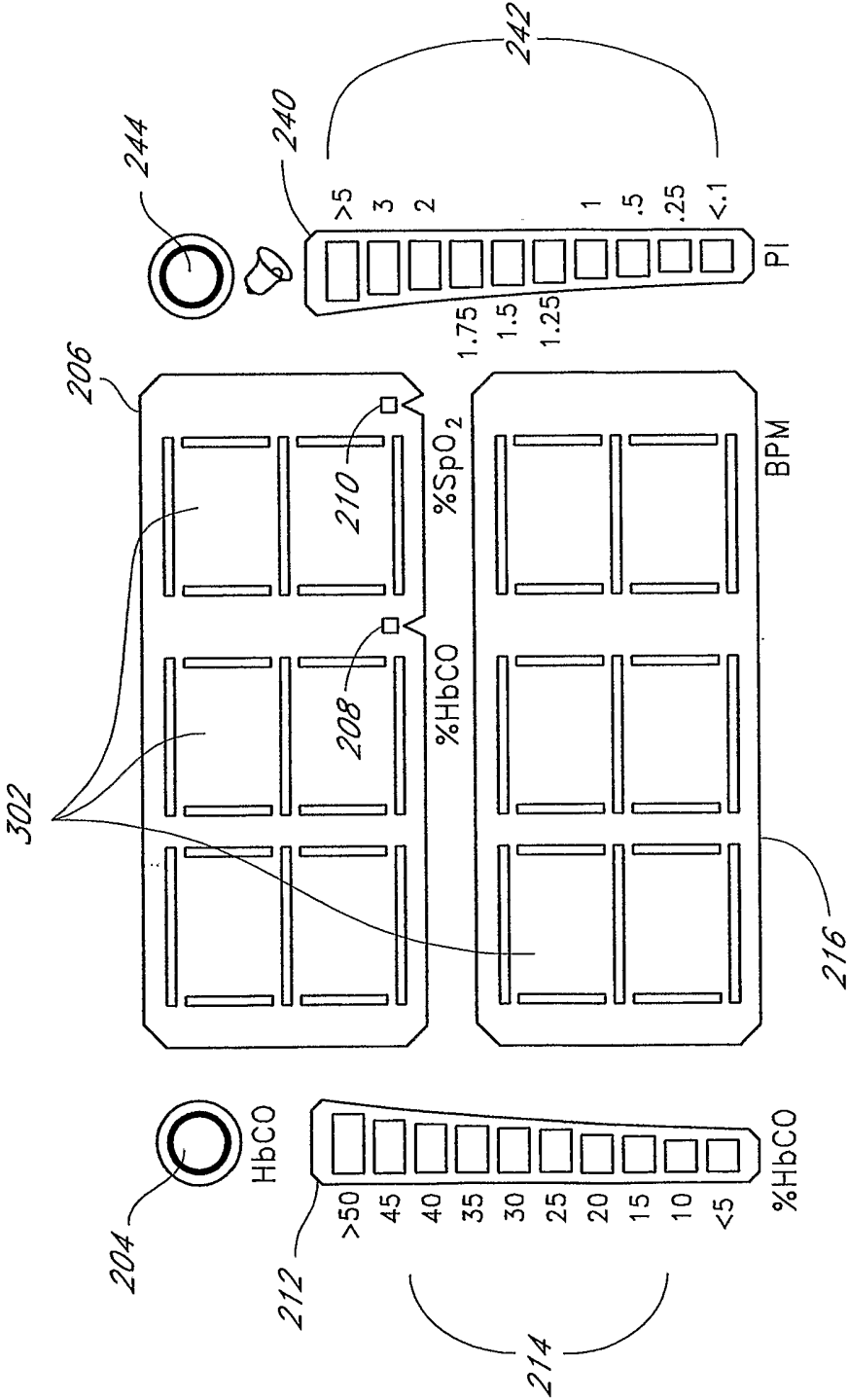
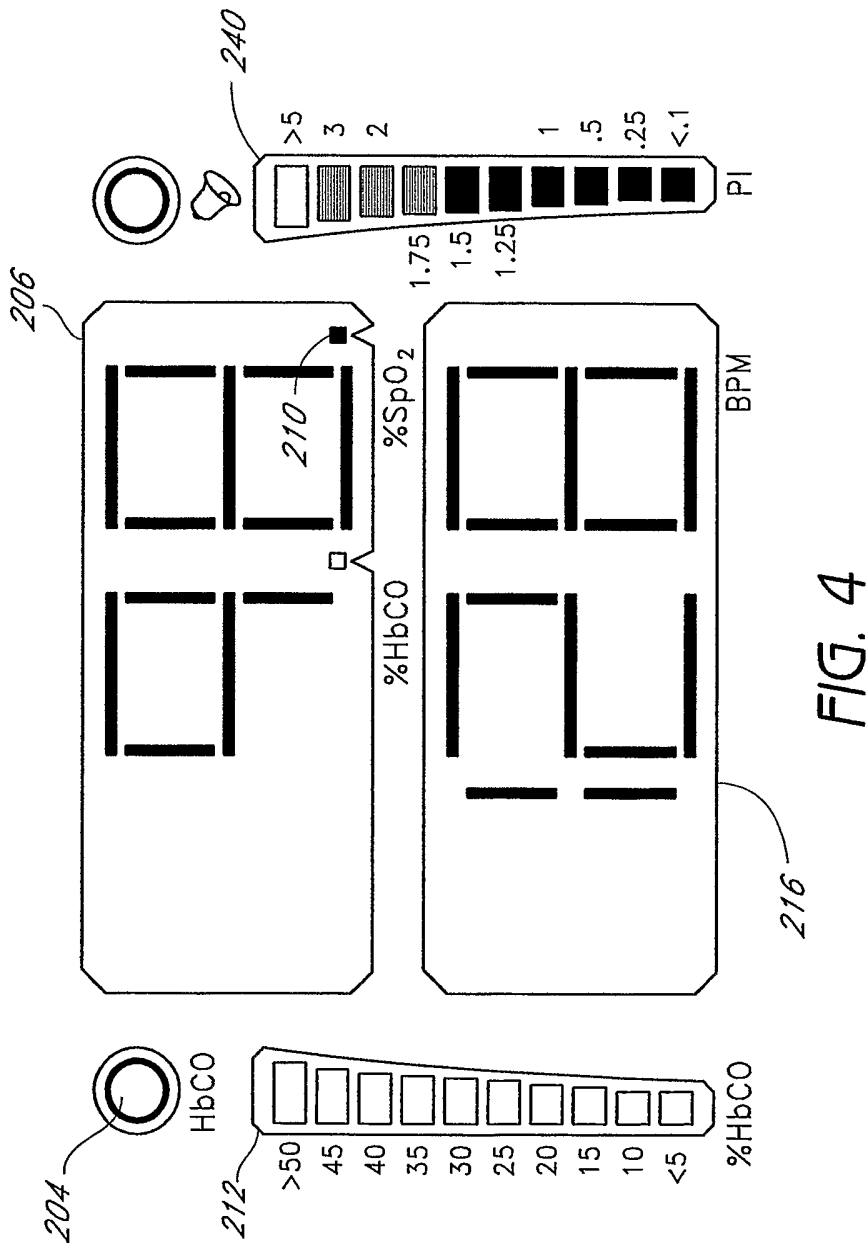
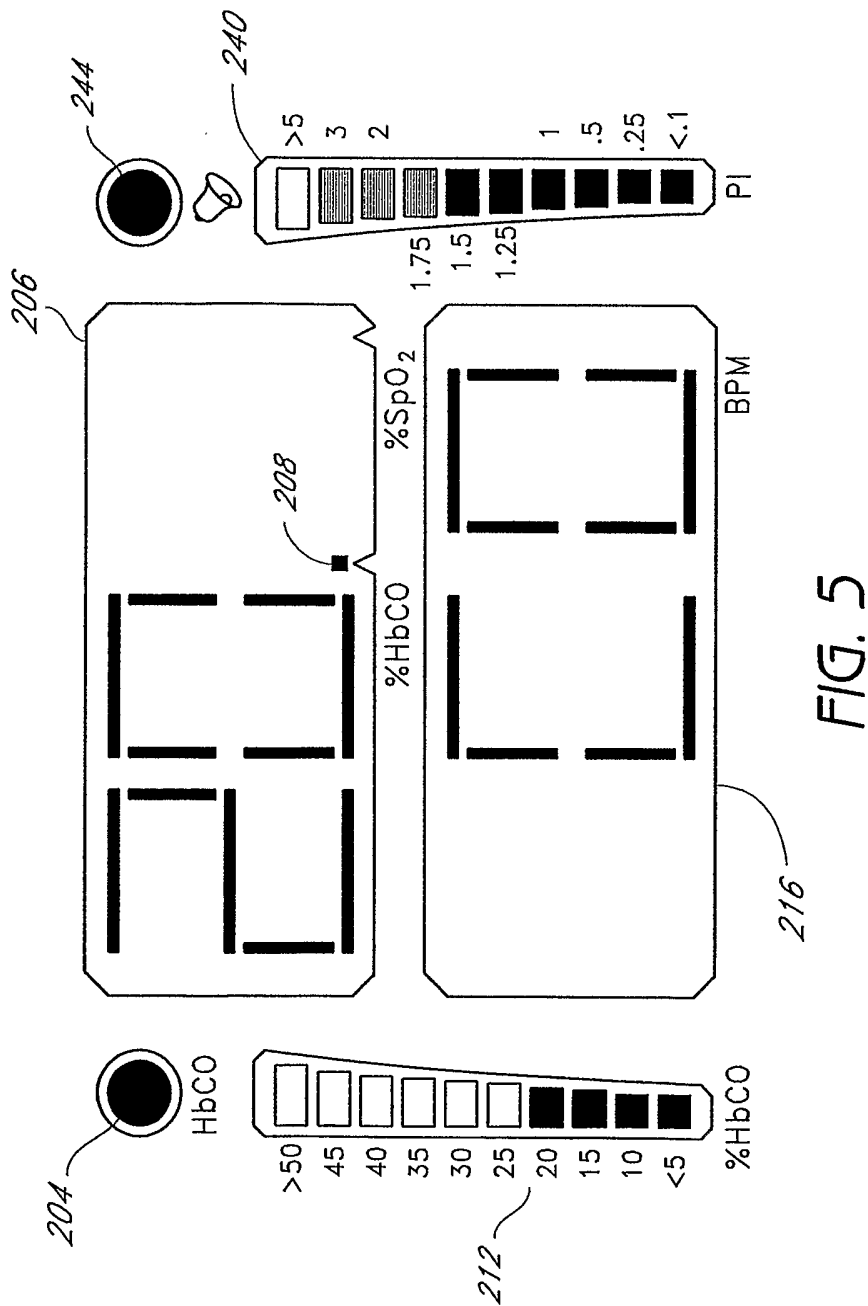


FIG. 3





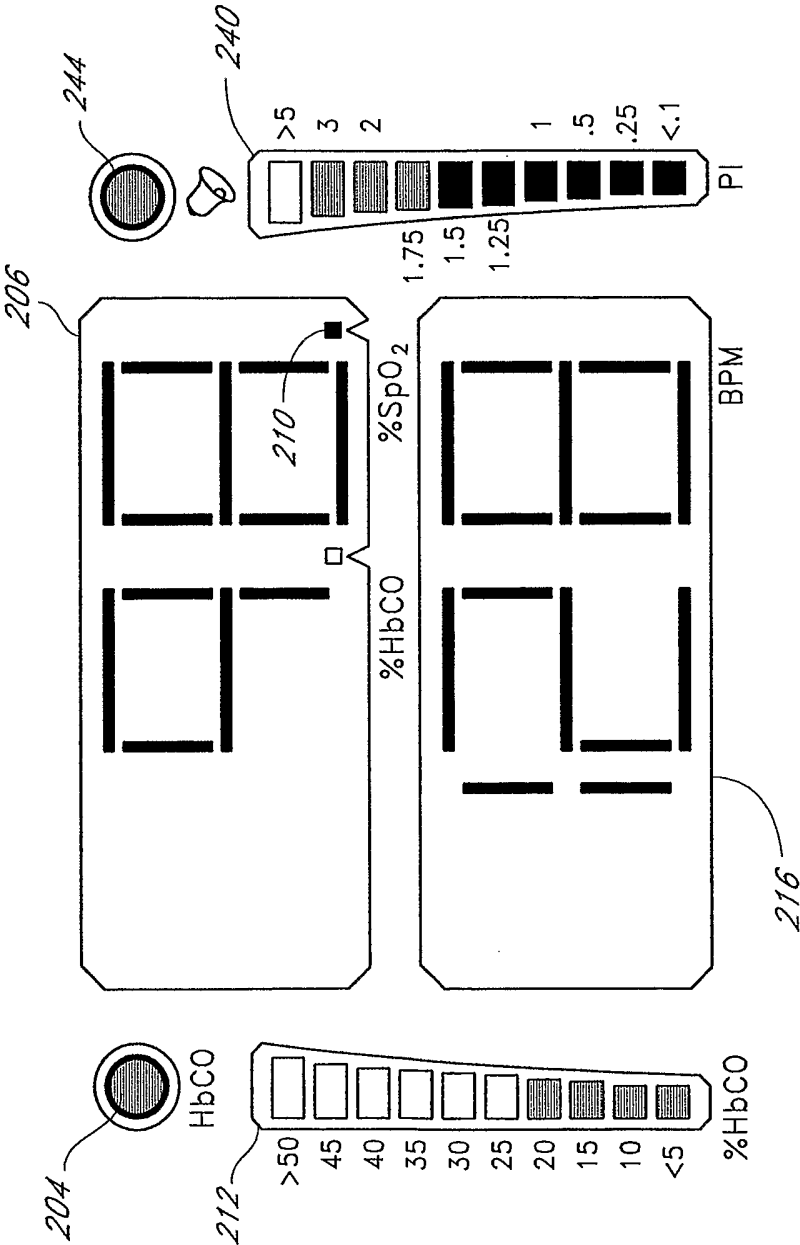


FIG. 6

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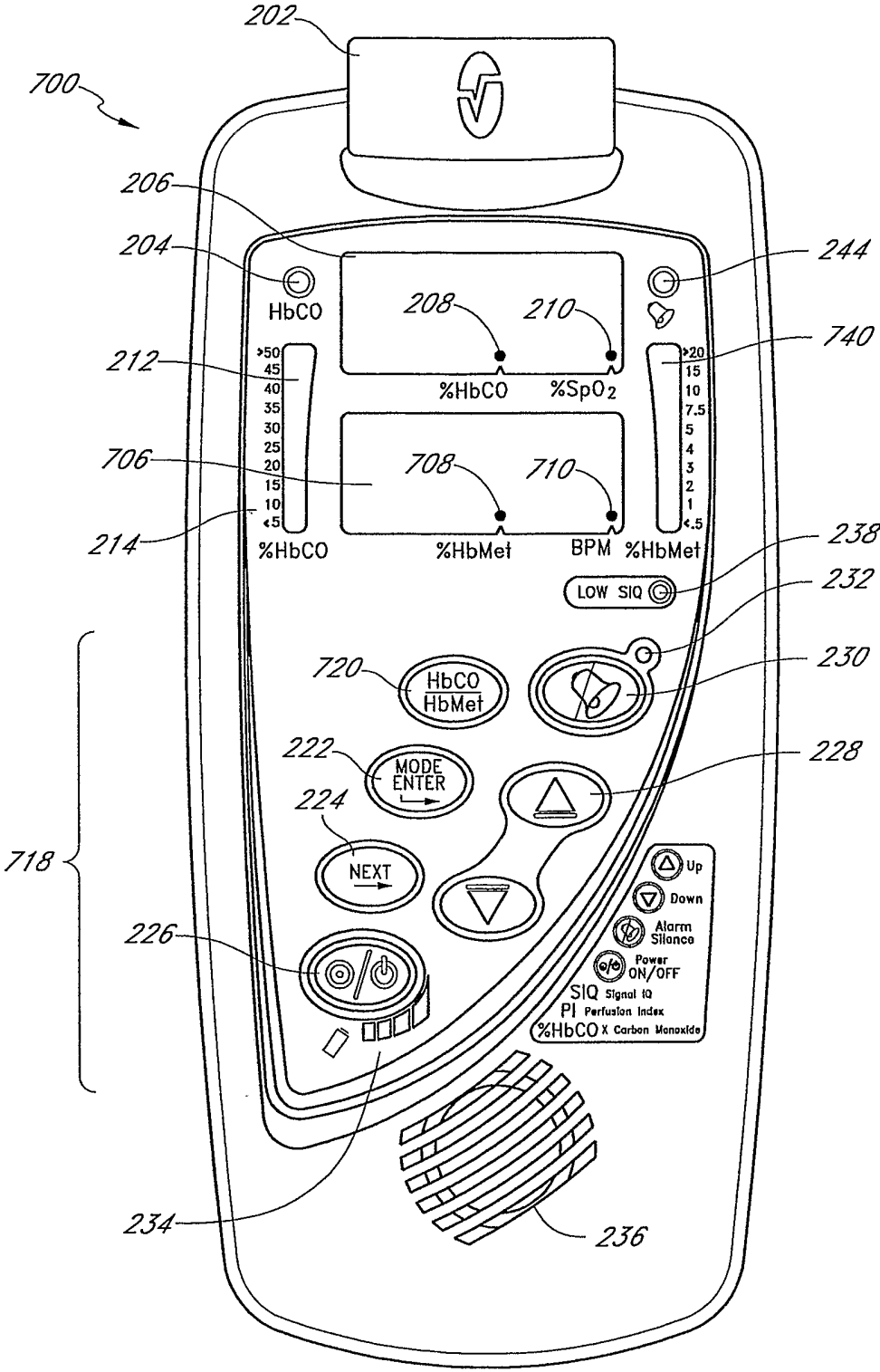


FIG. 7

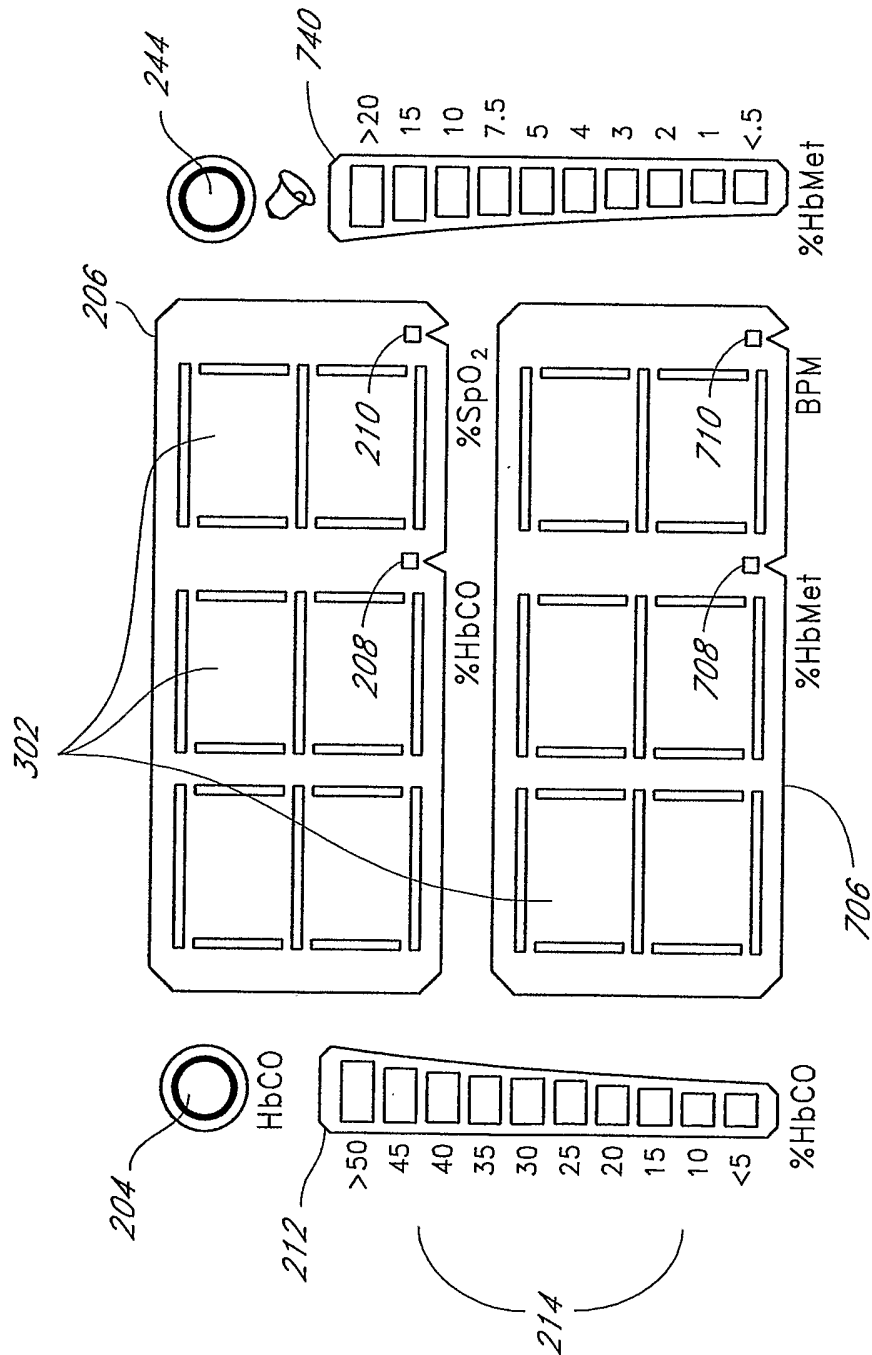


FIG. 8

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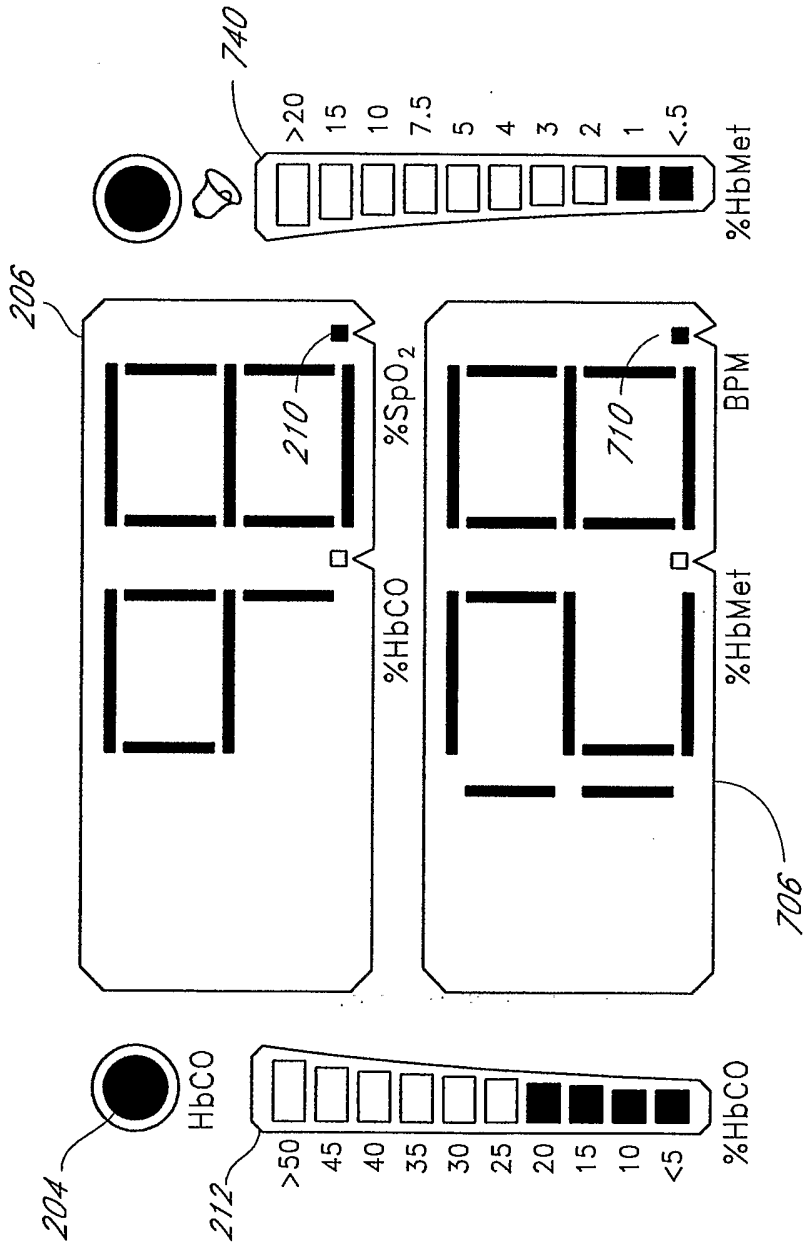


FIG. 9

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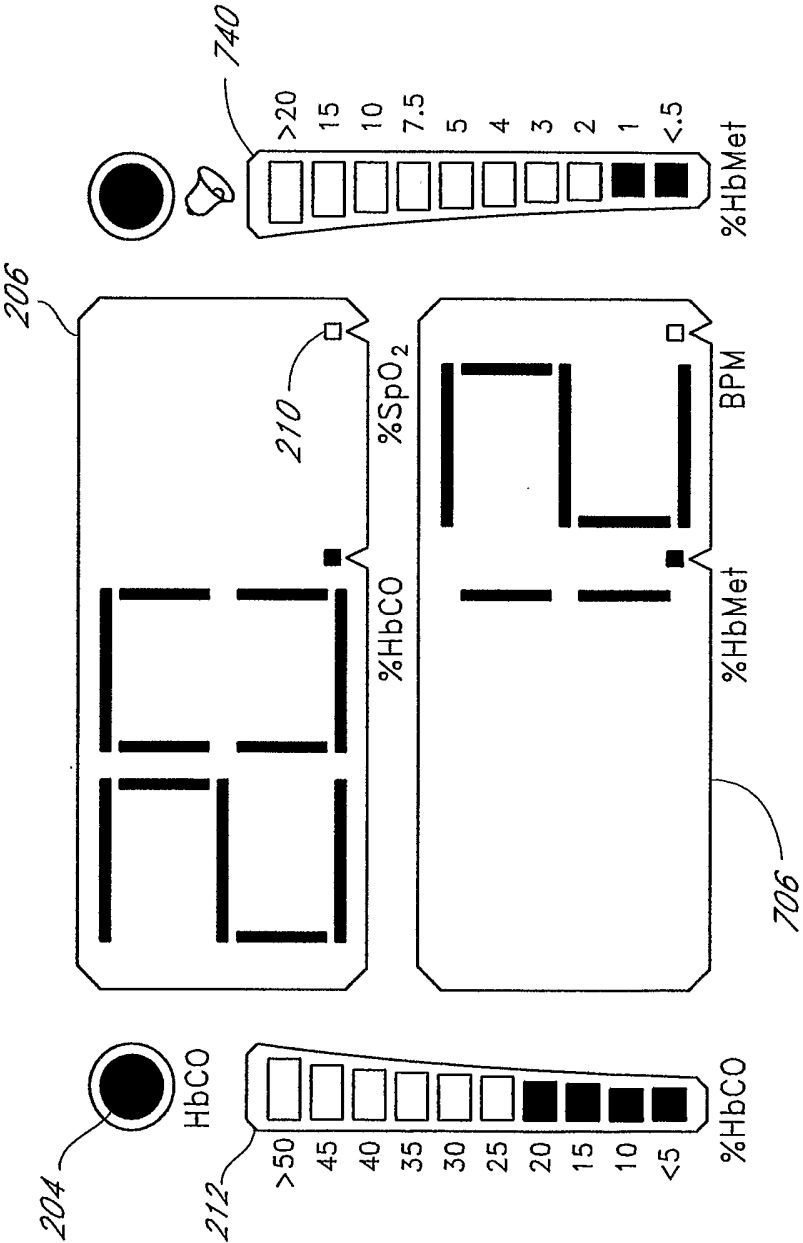


FIG. 10

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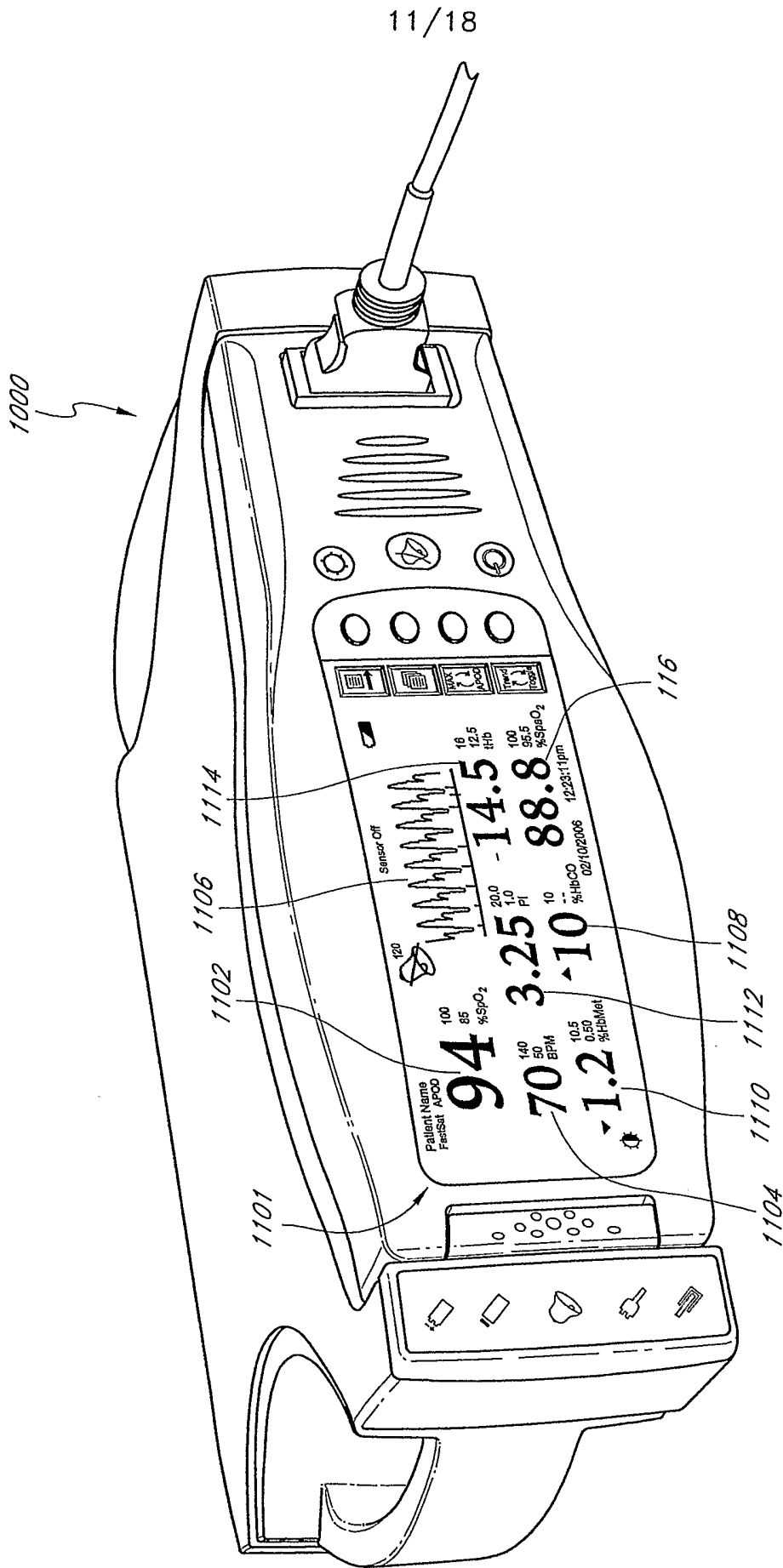


FIG. 11A

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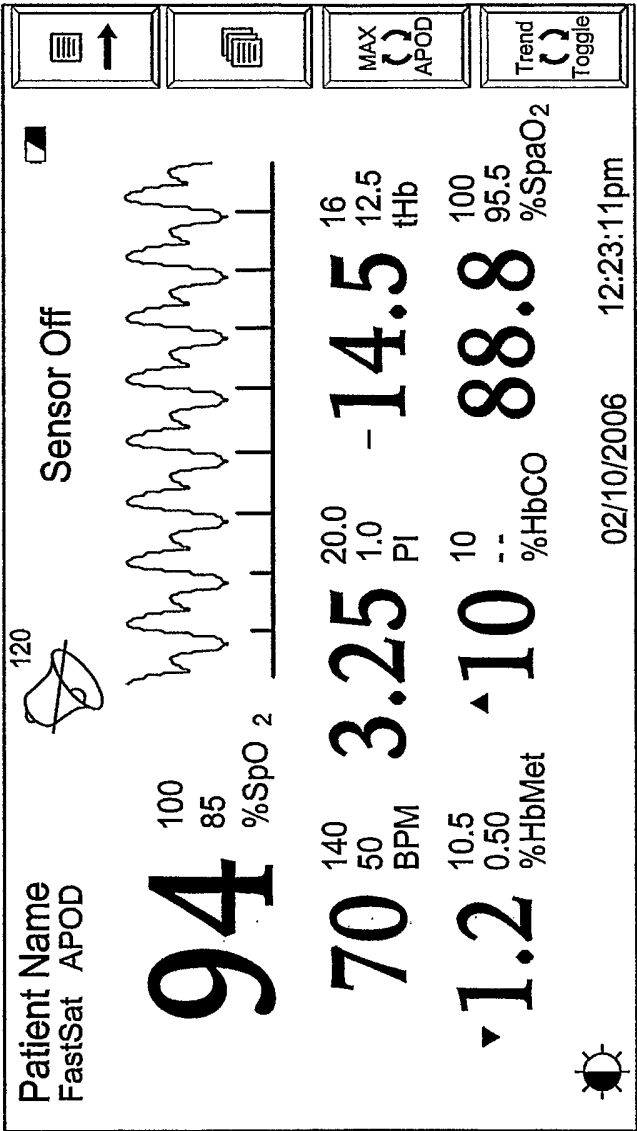


FIG. 11B

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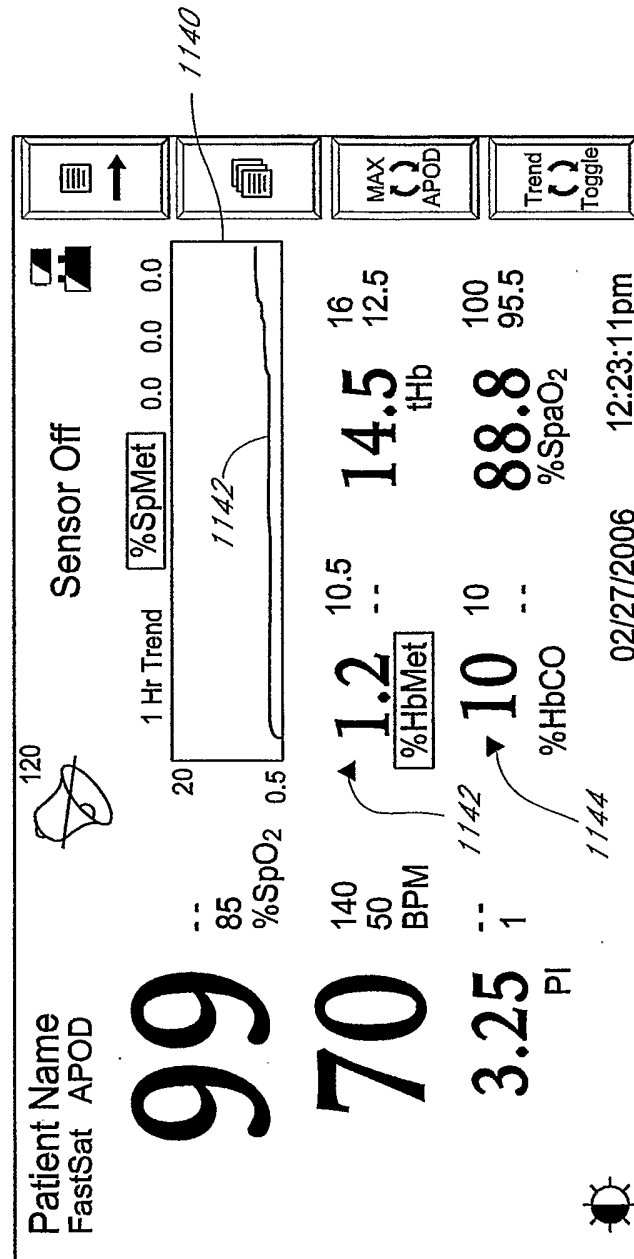


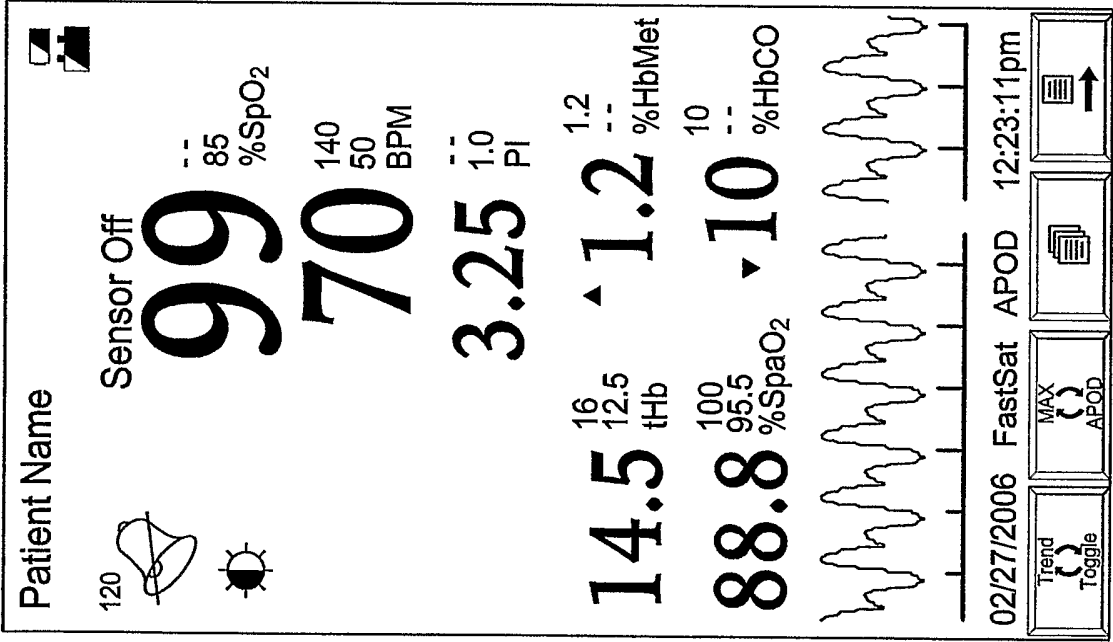
FIG. 11C

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FIG. 11D



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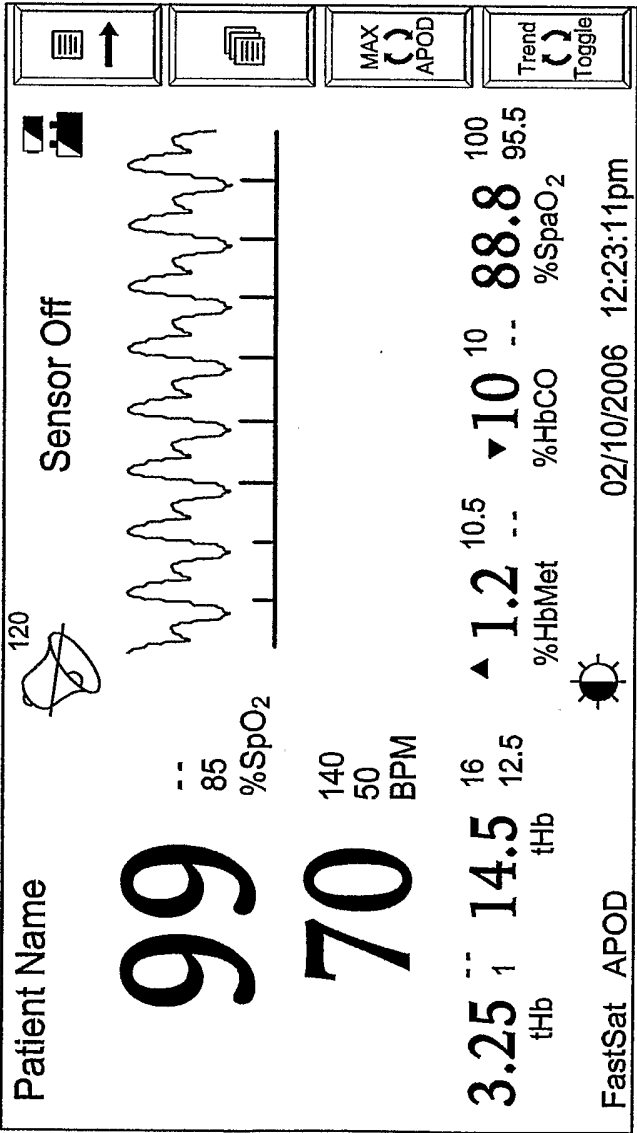


FIG. 11E

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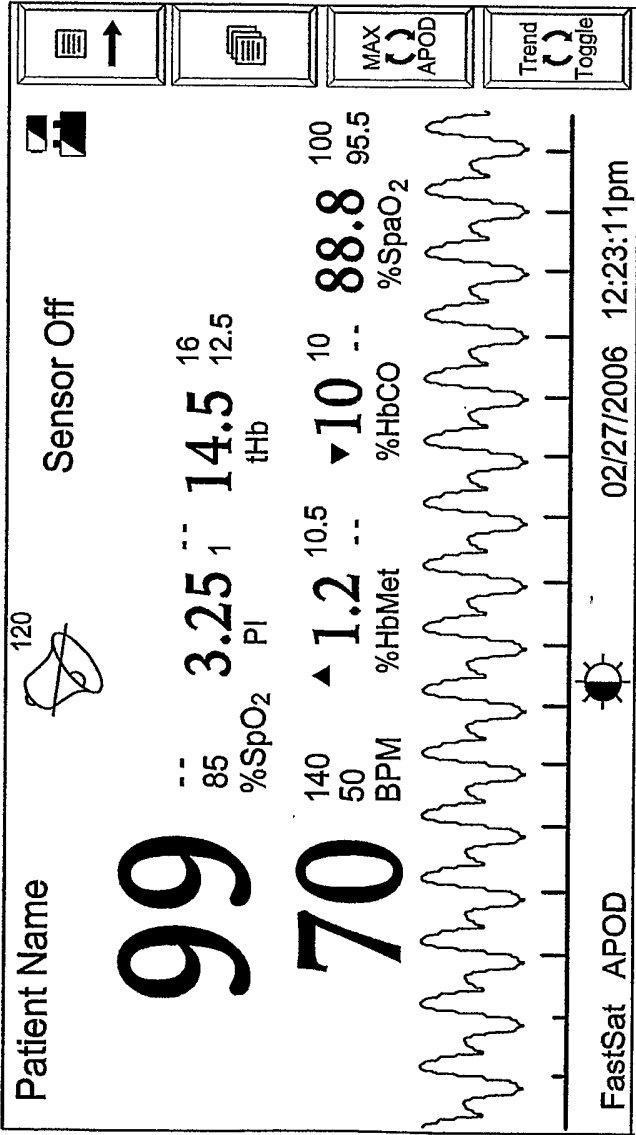


FIG. 11F

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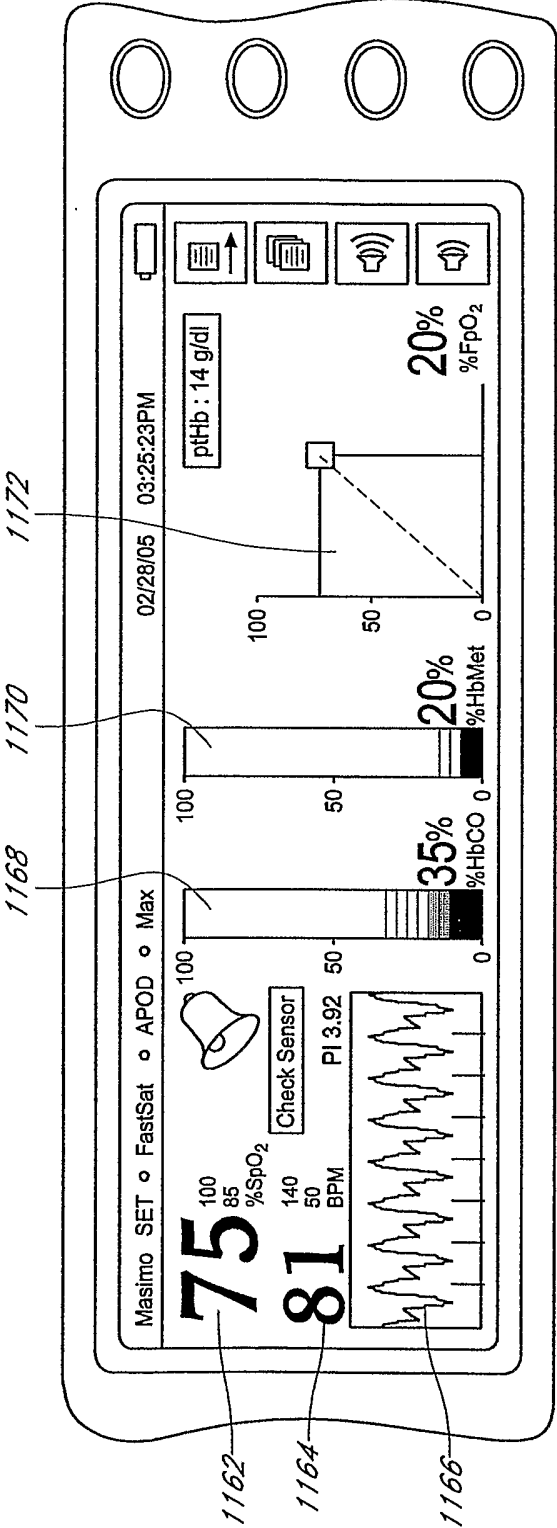


FIG. 11G

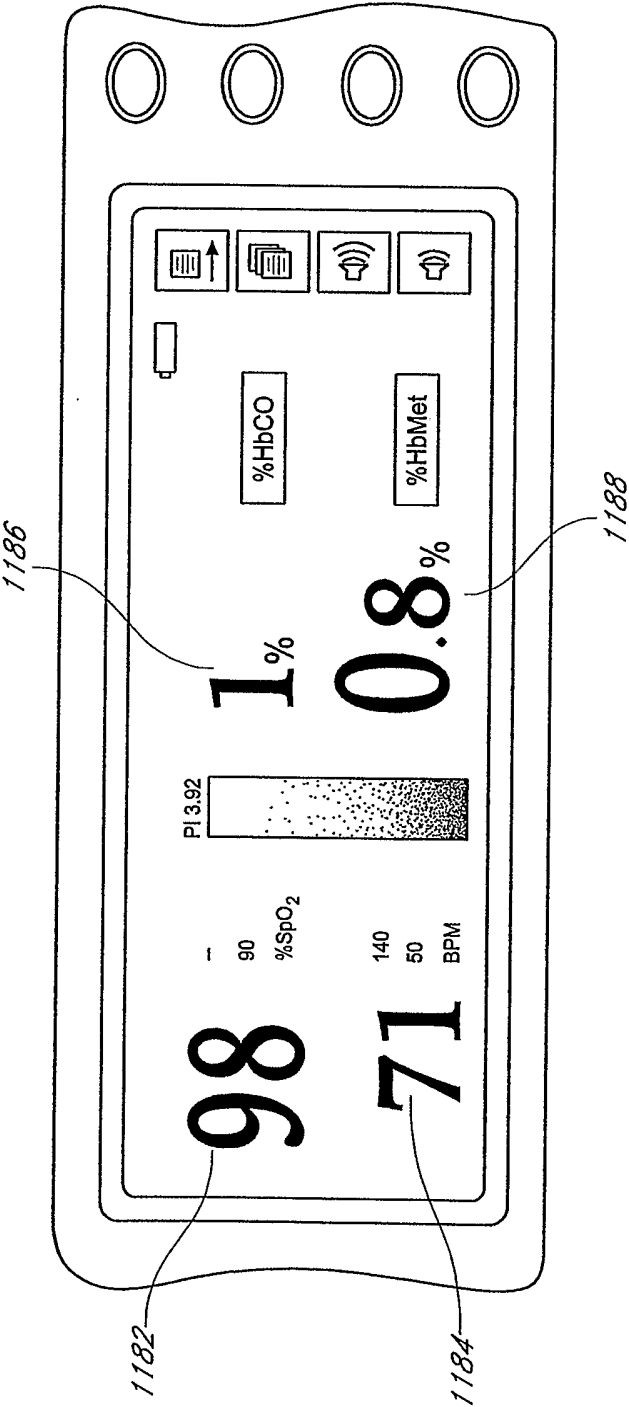


FIG. 11H

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2006/007536

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B5/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 645 059 A (FEIN ET AL) 8 July 1997 (1997-07-08)	1-4, 18-22, 33-37
Y	column 1, line 50 - column 2, line 15 column 4, line 33 - line 61 figures 1-4	5-17, 23-32
X	US 5 058 588 A (KAESTLE ET AL) 22 October 1991 (1991-10-22)	1-4, 18-22, 33-37
	column 2, line 8 - column 3, line 36 column 6, line 62 - column 7, line 30 figures 1,5	
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☒ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents :

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L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

O document referring to an oral disclosure, use, exhibition or other means

P document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

G document member of the same patent family

Date of the actual completion of the international search

21 June 2006

Date of mailing of the international search report

17/07/2006

Name and mailing address of the ISA/

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INTERNATIONAL SEARCH REPORT

International application No
PCT/US2006/007536

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

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INTERNATIONAL SEARCH REPORT

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EXHIBIT 8



US010736507B2

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Muhsin et al.

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(45) **Date of Patent:** **Aug. 11, 2020**

(54) **PHYSIOLOGICAL MONITOR WITH
MOBILE COMPUTING DEVICE
CONNECTIVITY**

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20, 2012.

(51) **Int. Cl.**

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A61B 5/0476 (2006.01)
A61B 5/0402 (2006.01)
A61B 5/0205 (2006.01)
A61B 5/00 (2006.01)
A61B 7/00 (2006.01)

(52) **U.S. Cl.**

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(2013.01); **A61B 5/0402** (2013.01); **A61B**
5/0476 (2013.01); **A61B 5/14551** (2013.01);
A61B 5/7203 (2013.01); **A61B 5/7225**
(2013.01); **A61B 5/742** (2013.01); **A61B 7/003**
(2013.01); **A61B 2562/22** (2013.01)

(58) **Field of Classification Search**

None

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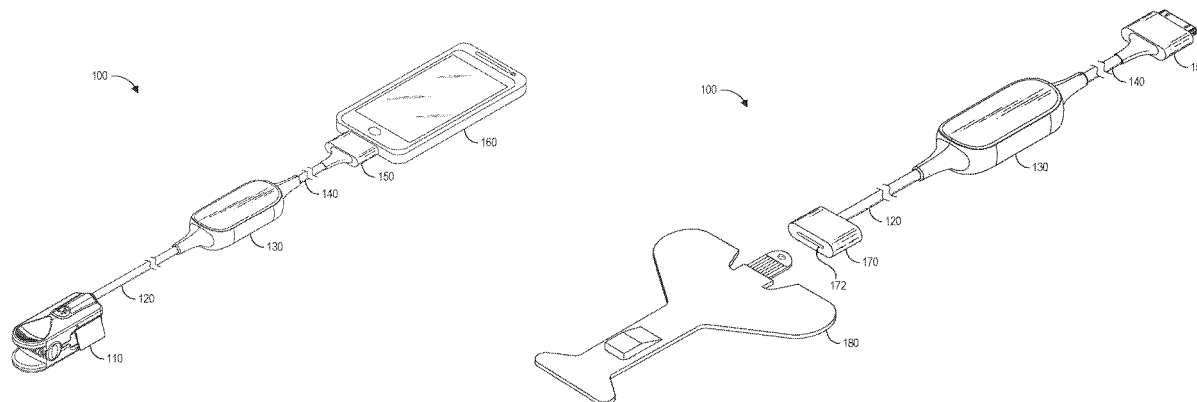
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& Bear, LLP

(57)

ABSTRACT

Systems and method for monitoring patient physiological data are presented herein. In one embodiment, a physiological sensor and a mobile computing device can be connected via a cable or cables, and a processing board can be connected between the sensor and the mobile computing device to conduct advanced signal processing on the data received from the sensor before the data is transmitted for display on the mobile computing device.

20 Claims, 15 Drawing Sheets



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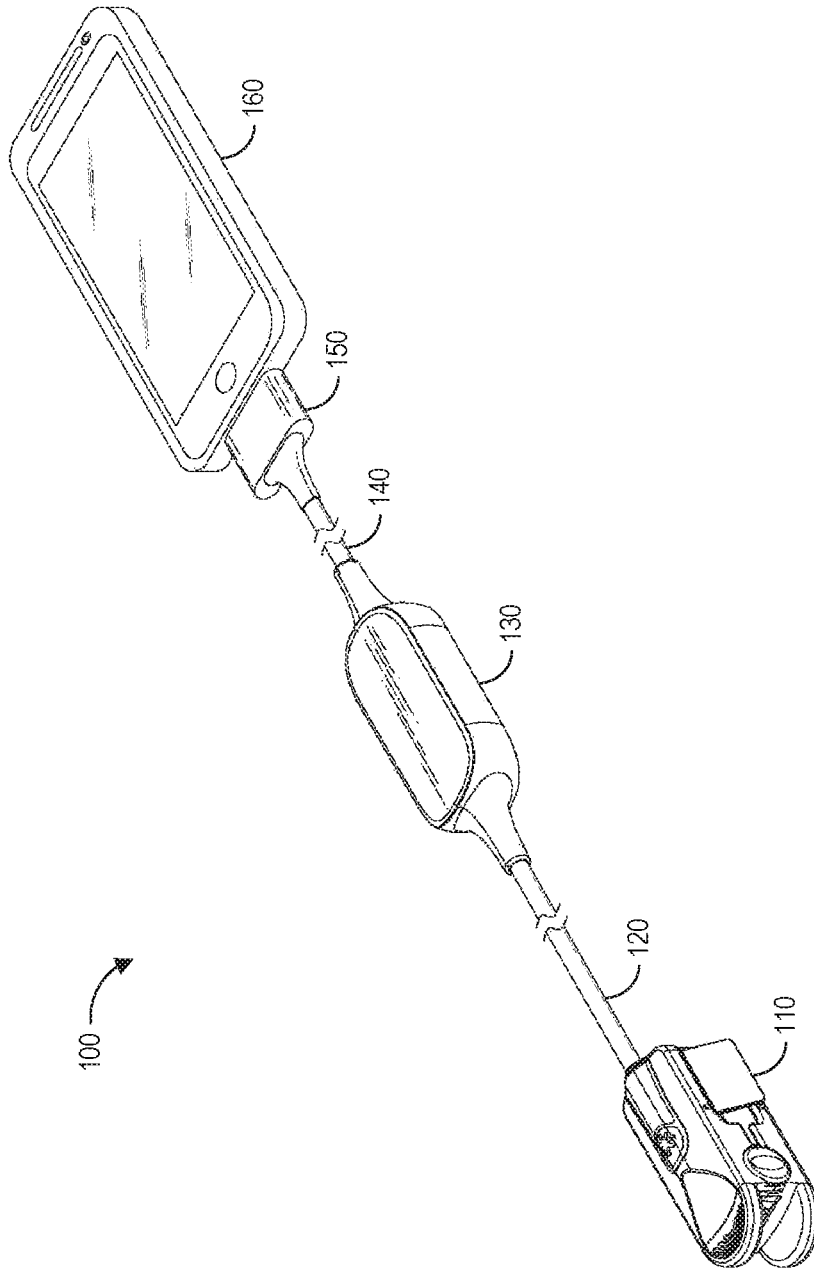


FIG. 1A

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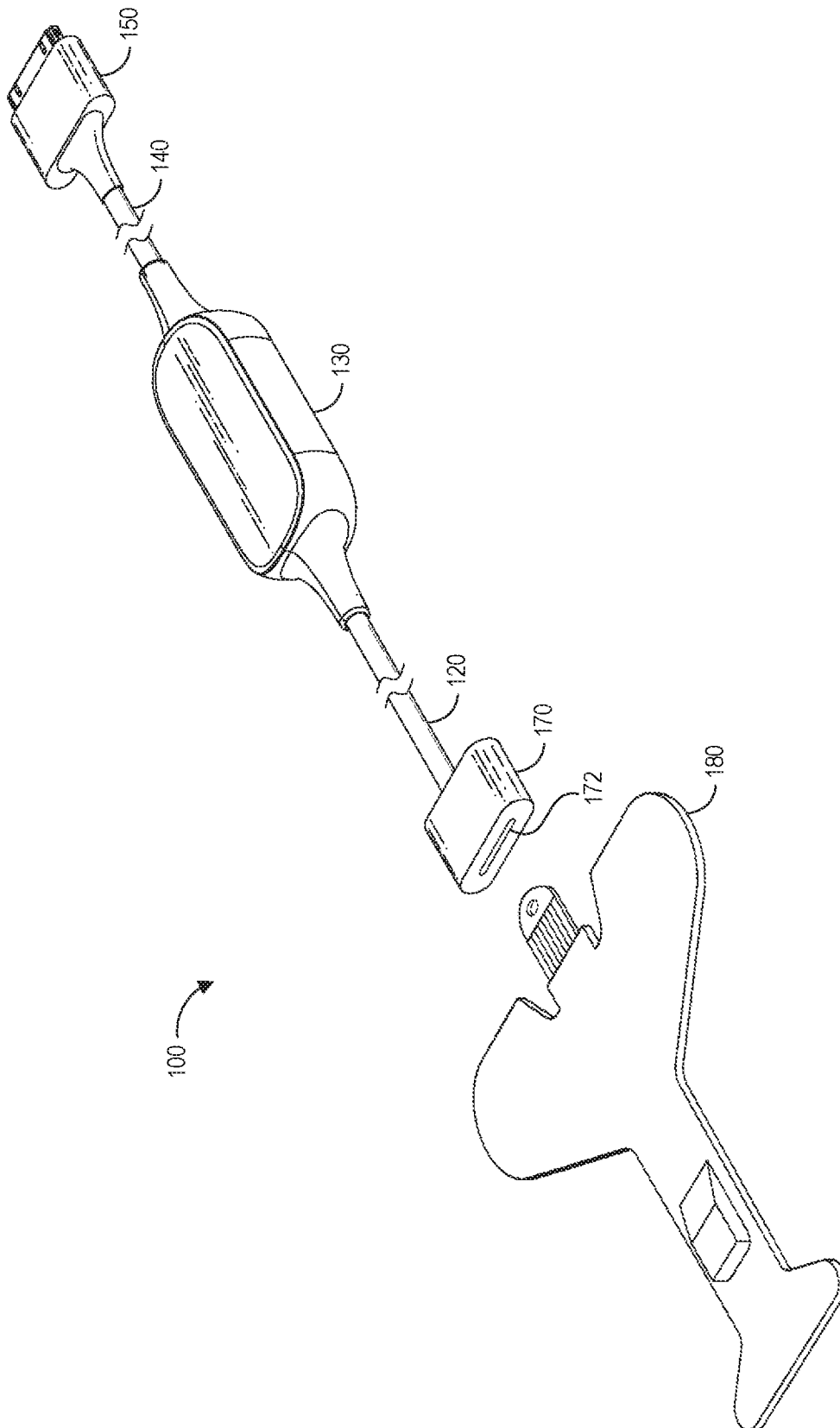


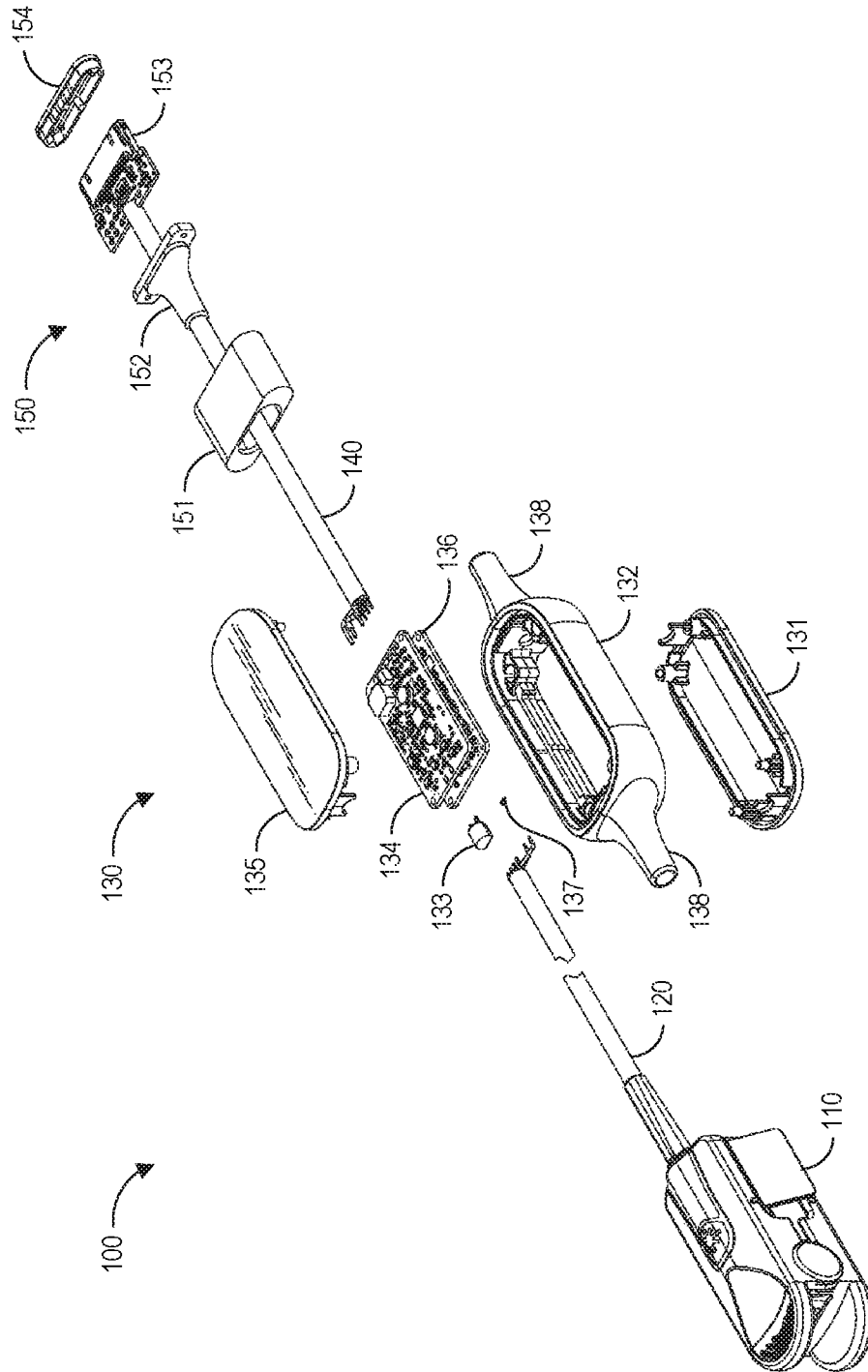
FIG. 1B

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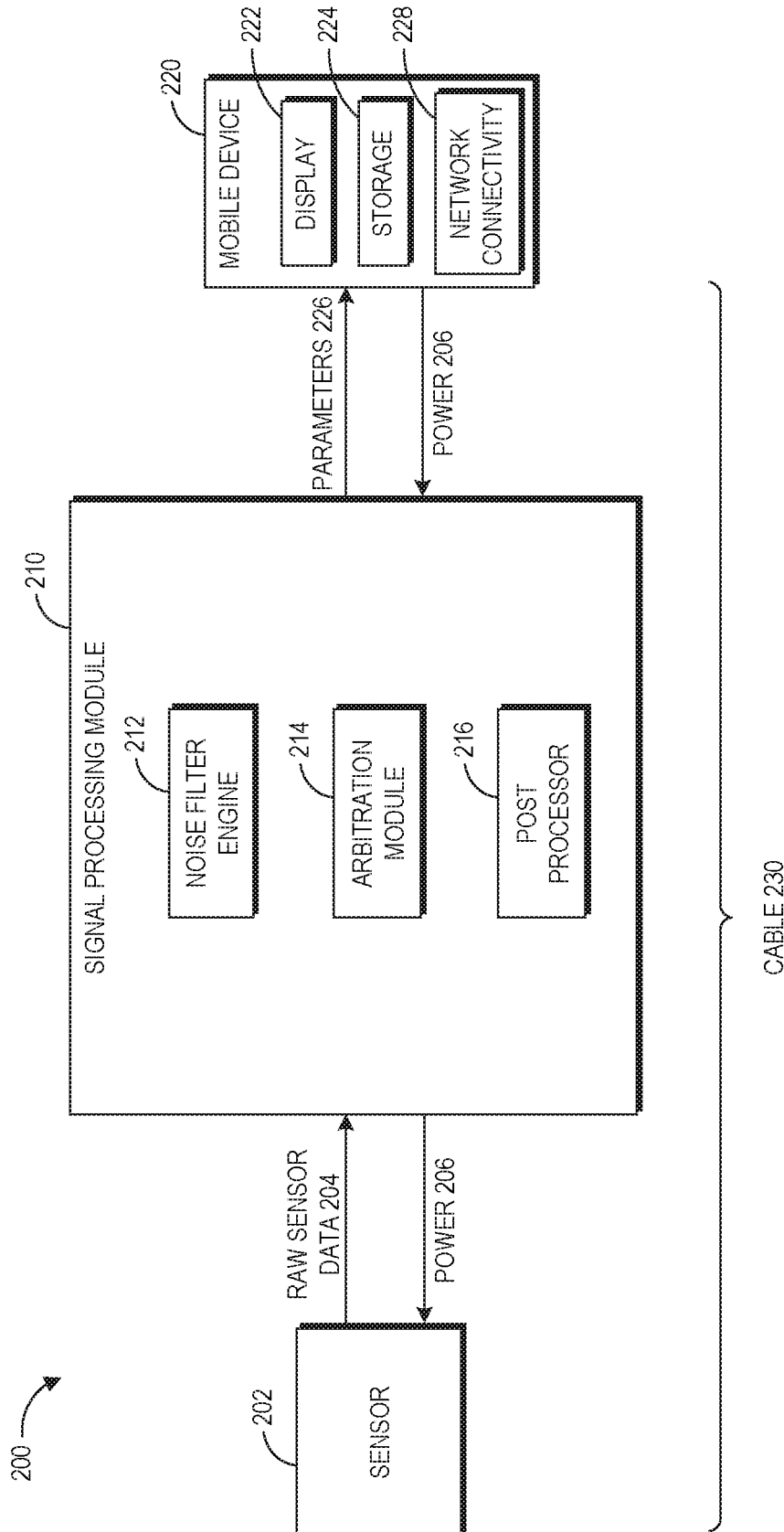


FIG. 2

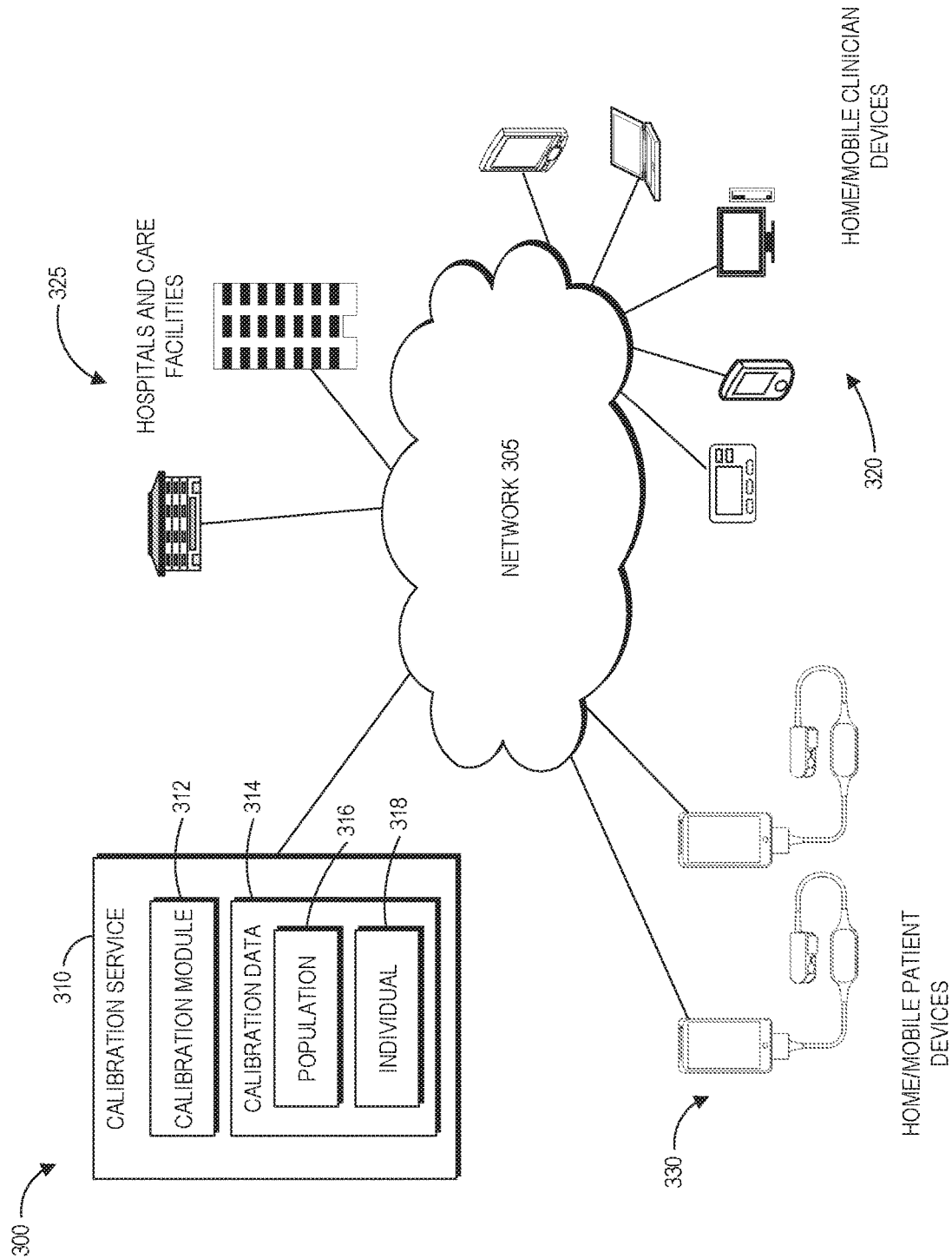


FIG. 3

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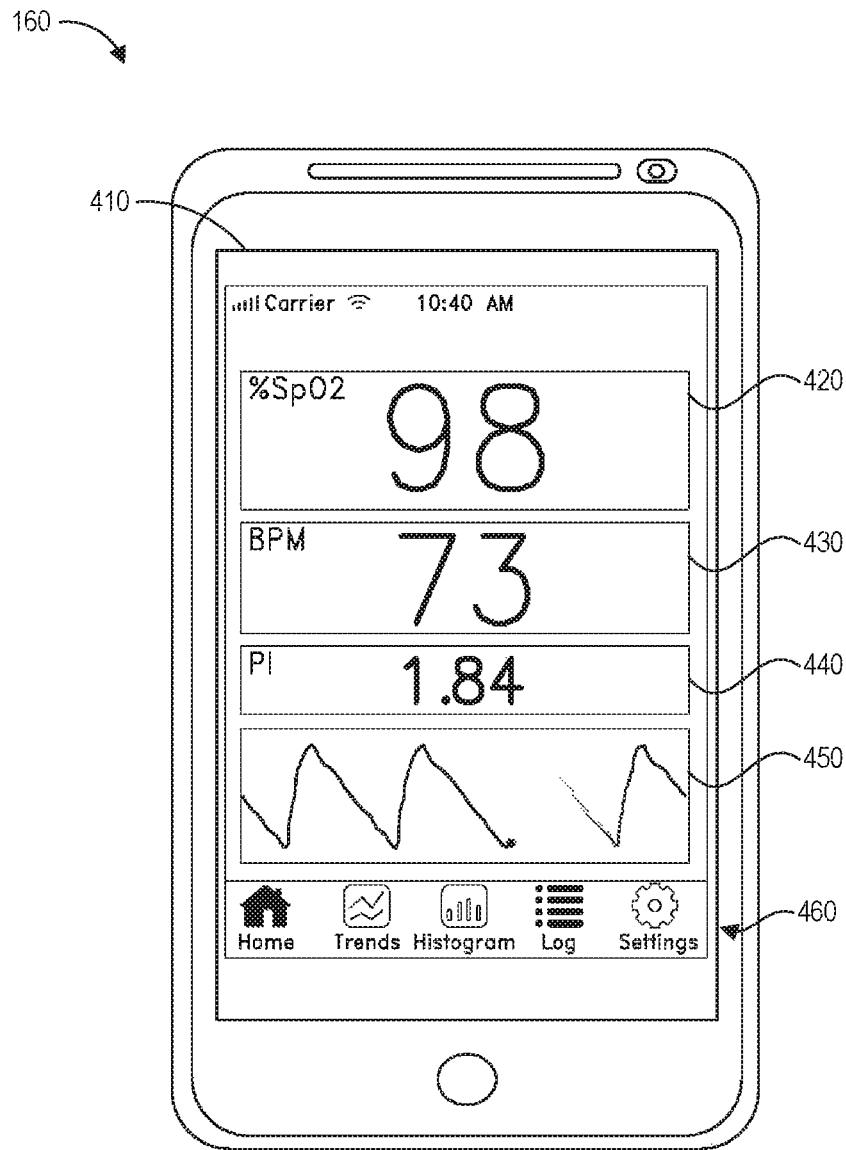


FIG. 4A

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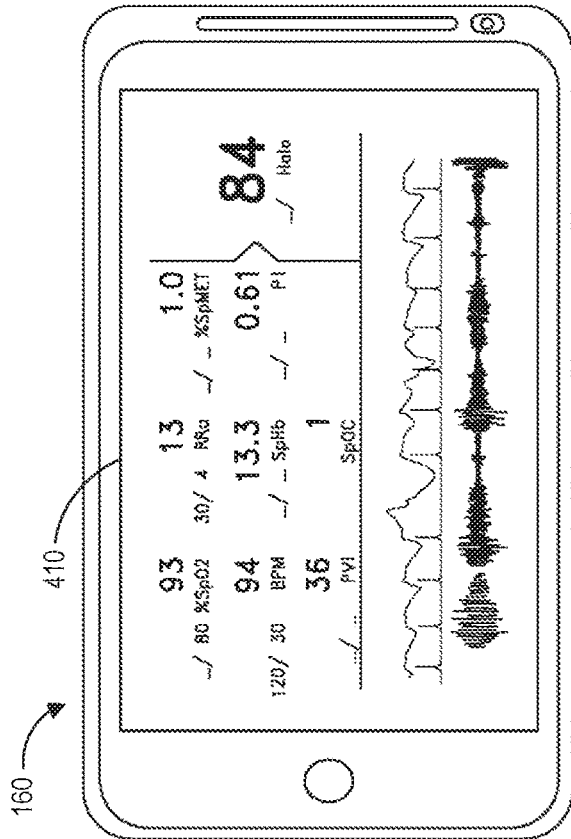


FIG. 4B

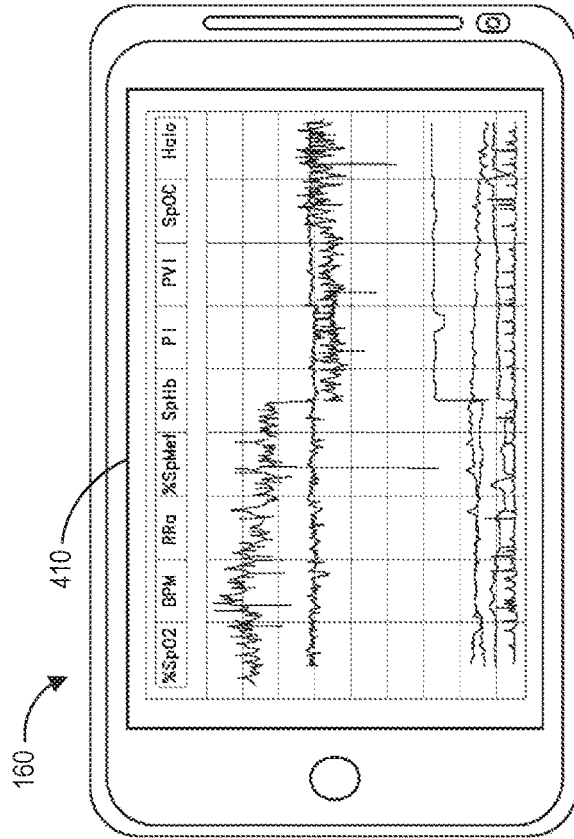


FIG. 4C

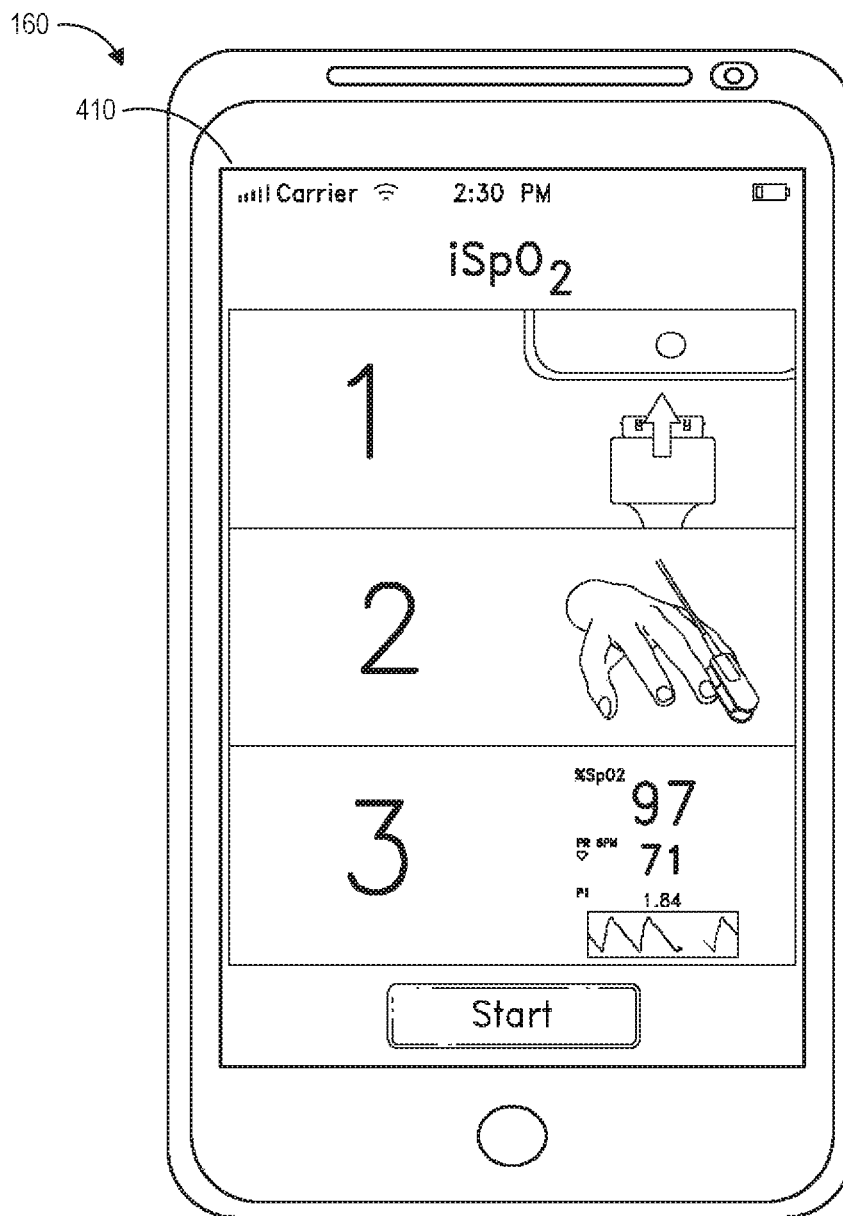


FIG. 4D

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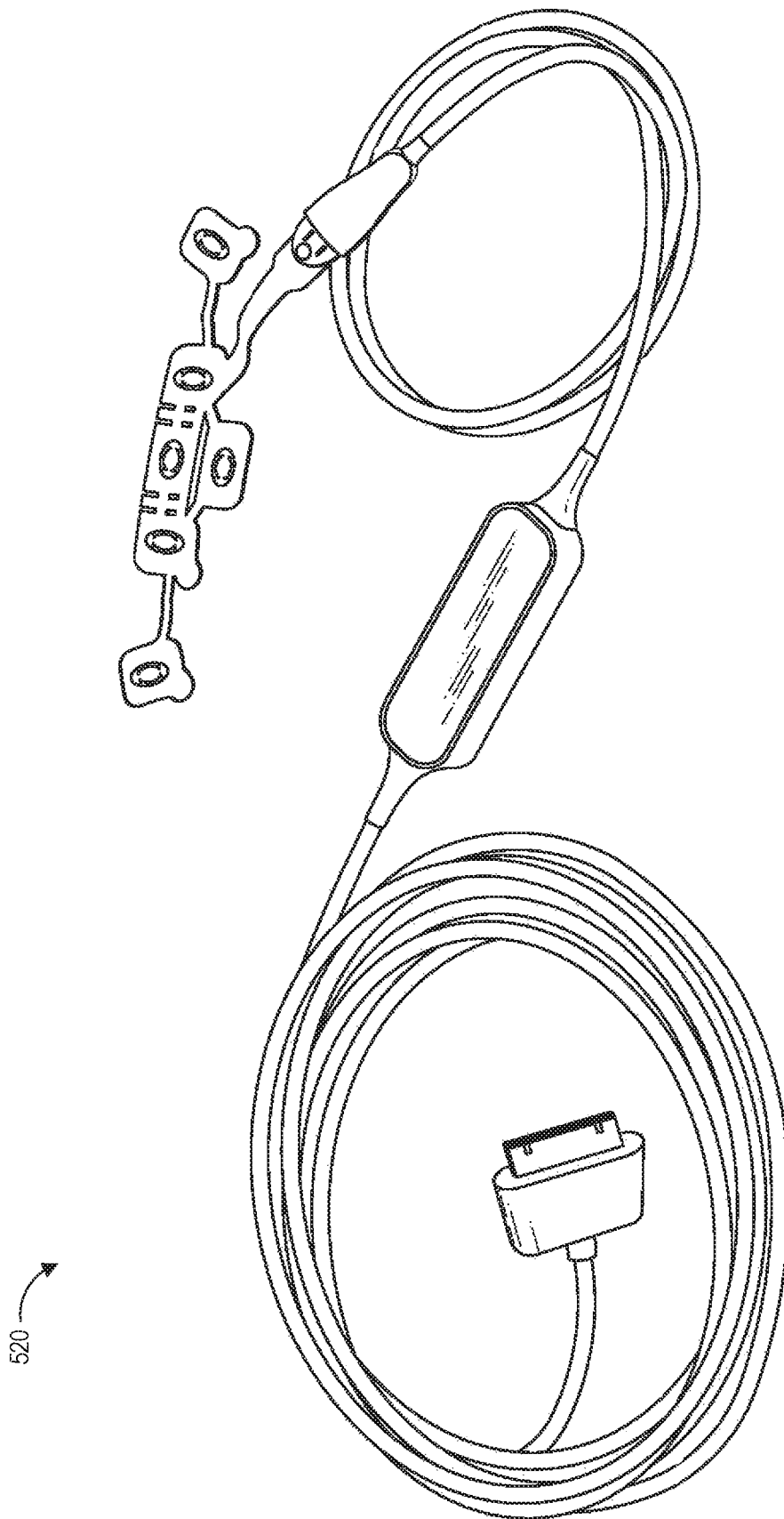
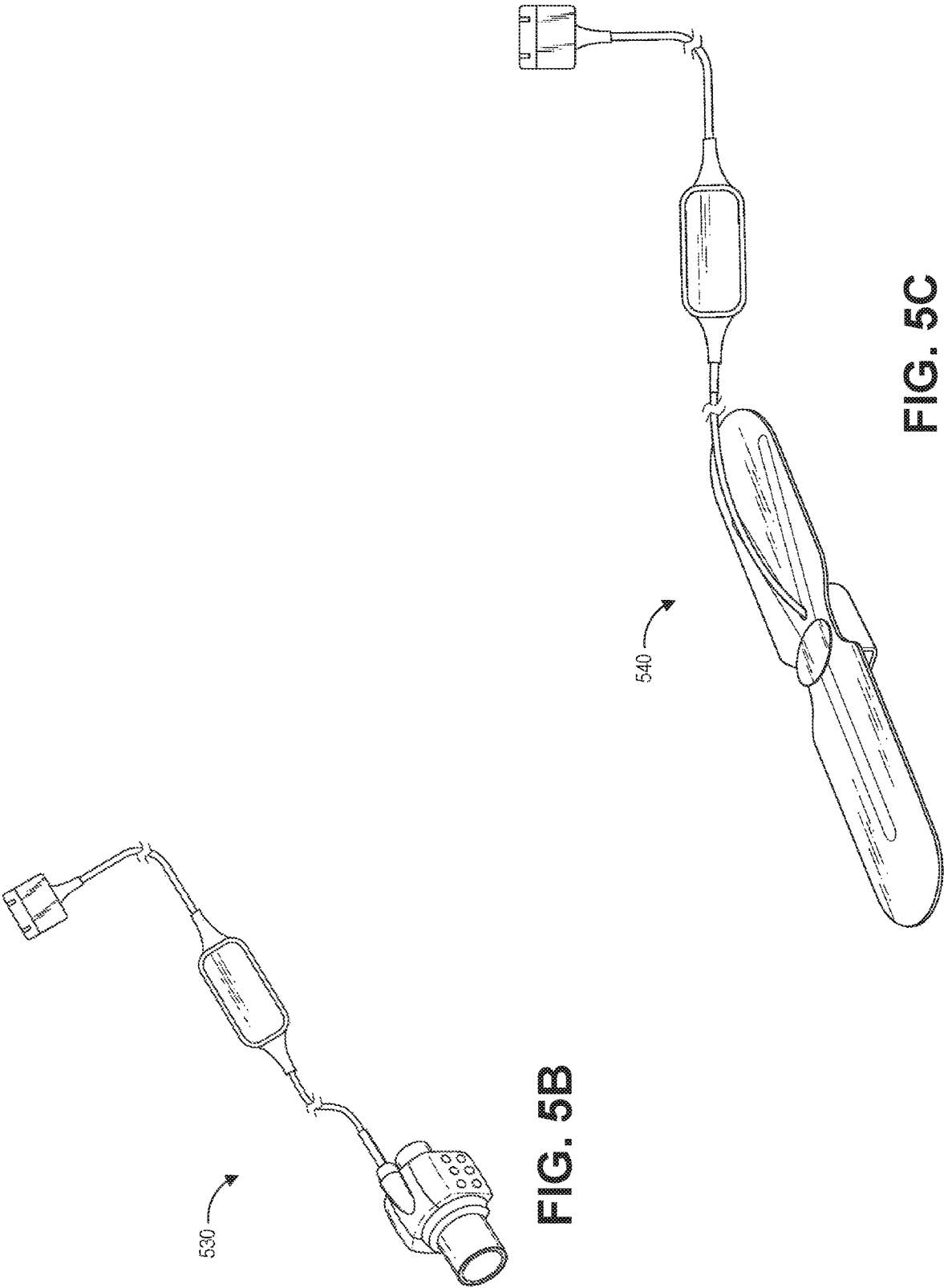


FIG. 5A



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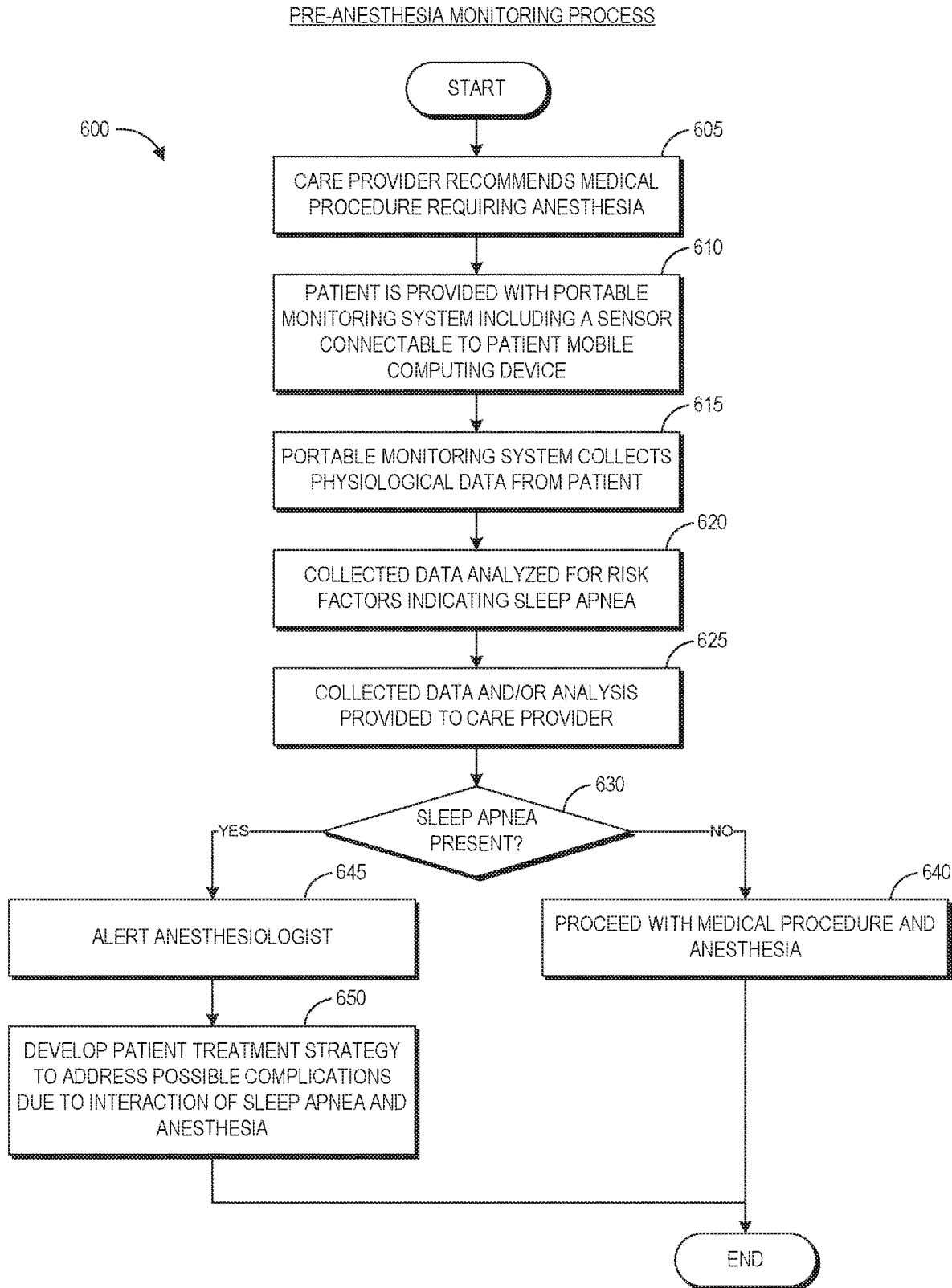


FIG. 6

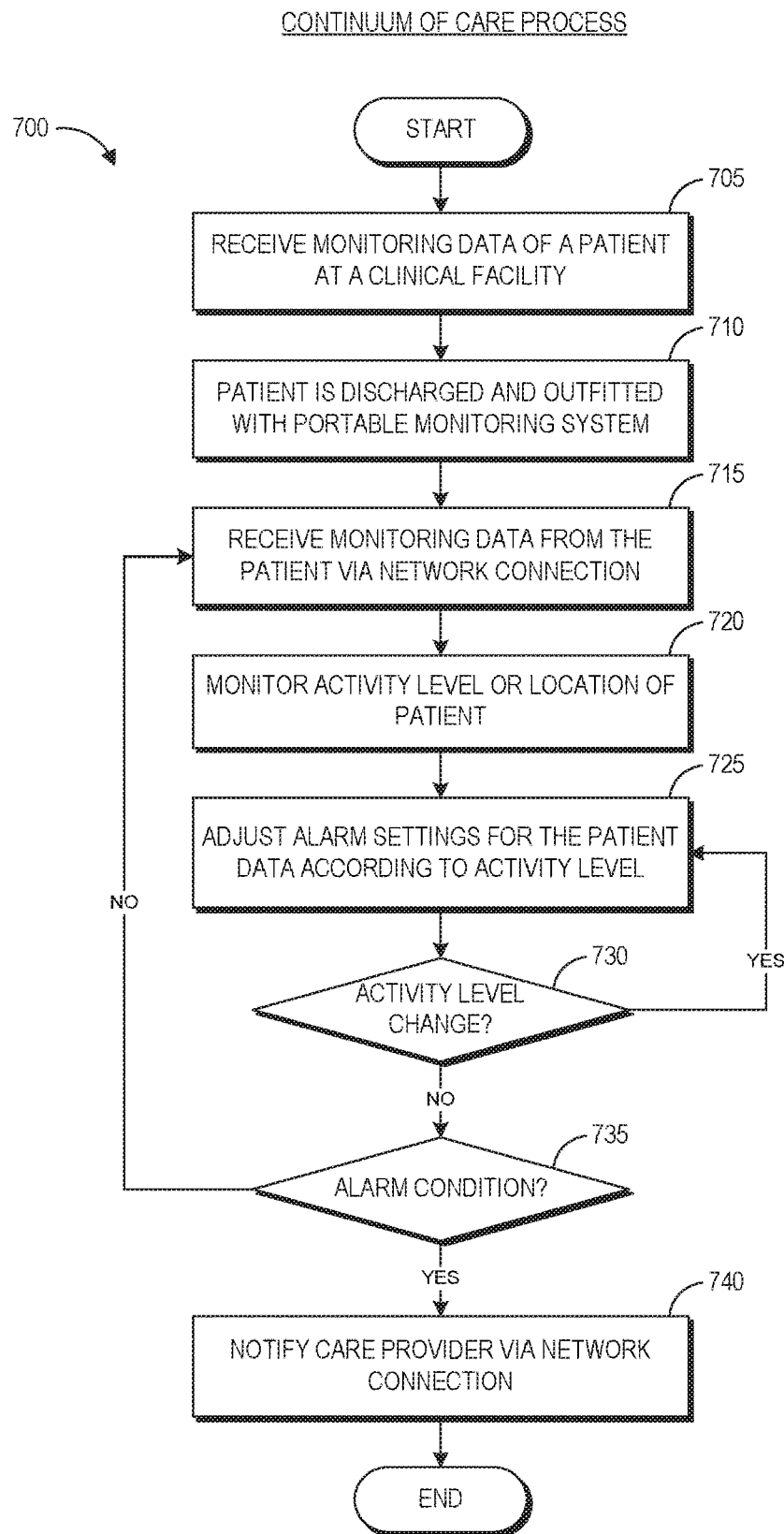


FIG. 7

MOBILE PHYSIOLOGICAL DATA MONITORING

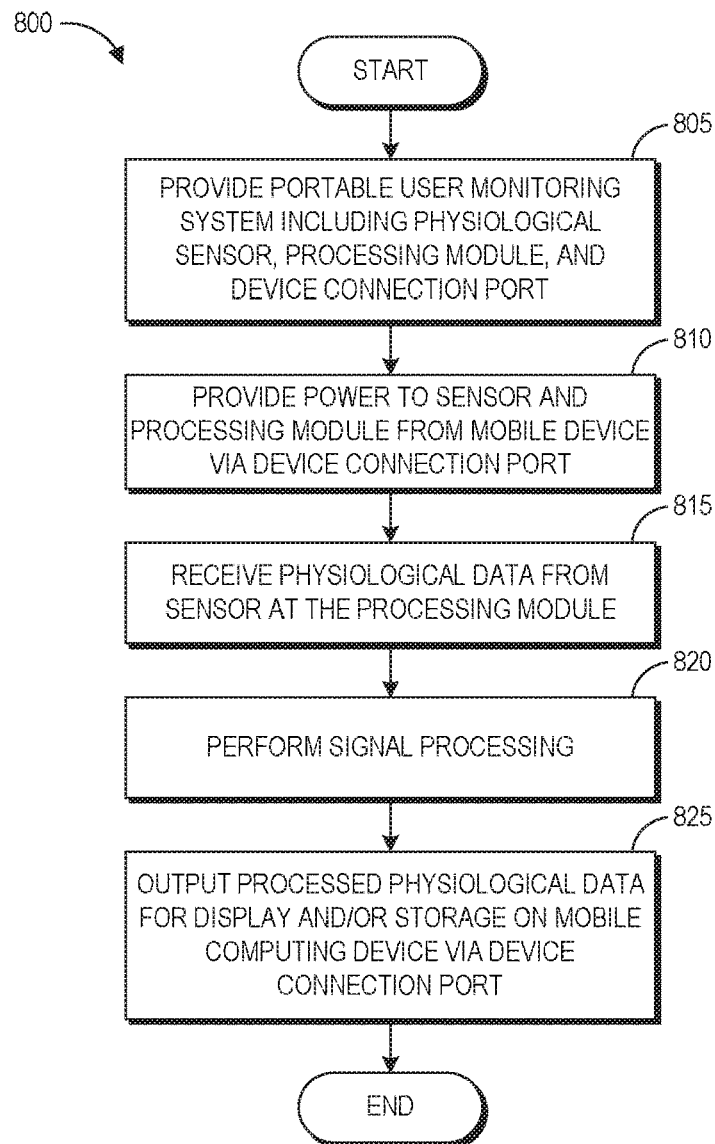


FIG. 8

USER-GUIDED MONITORING PROCESS

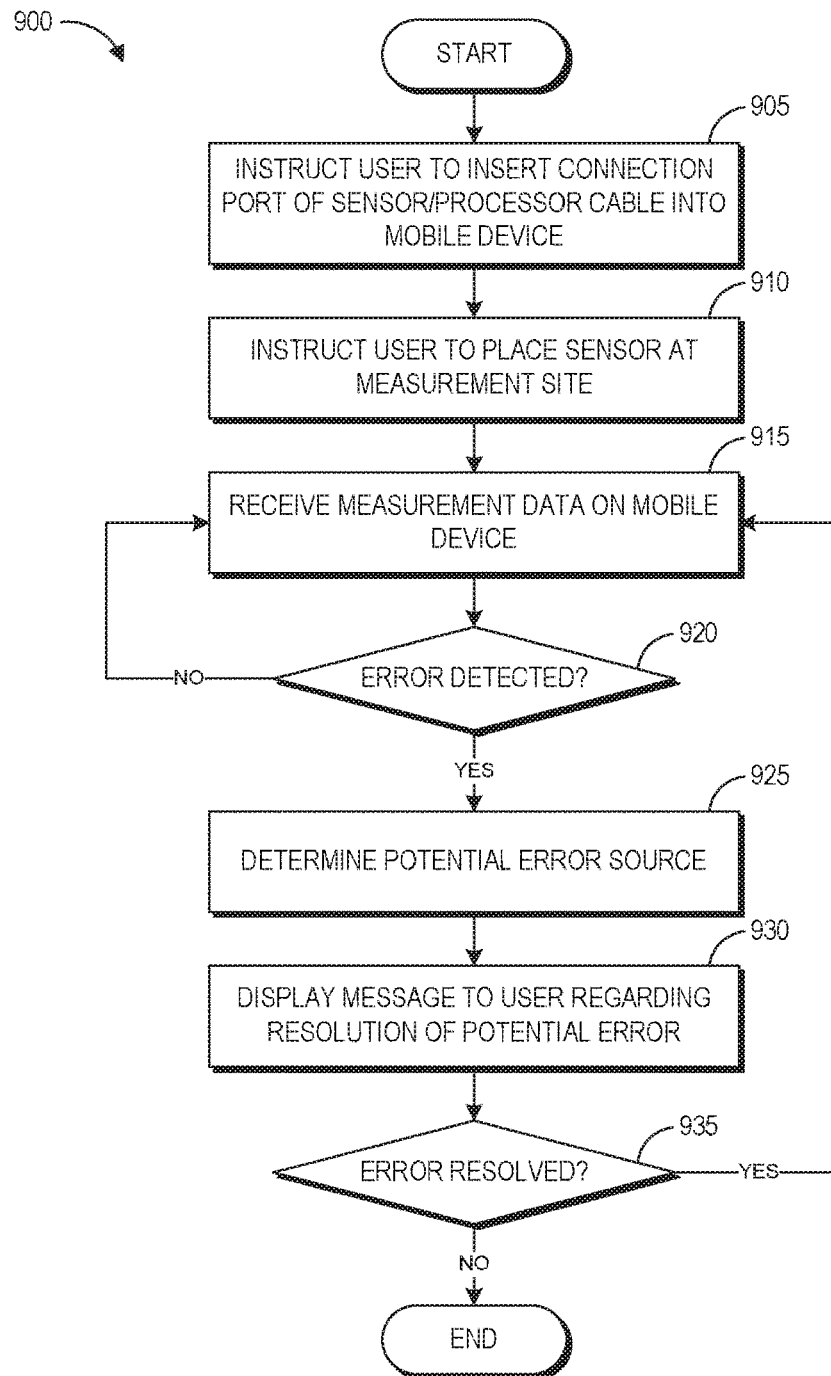


FIG. 9

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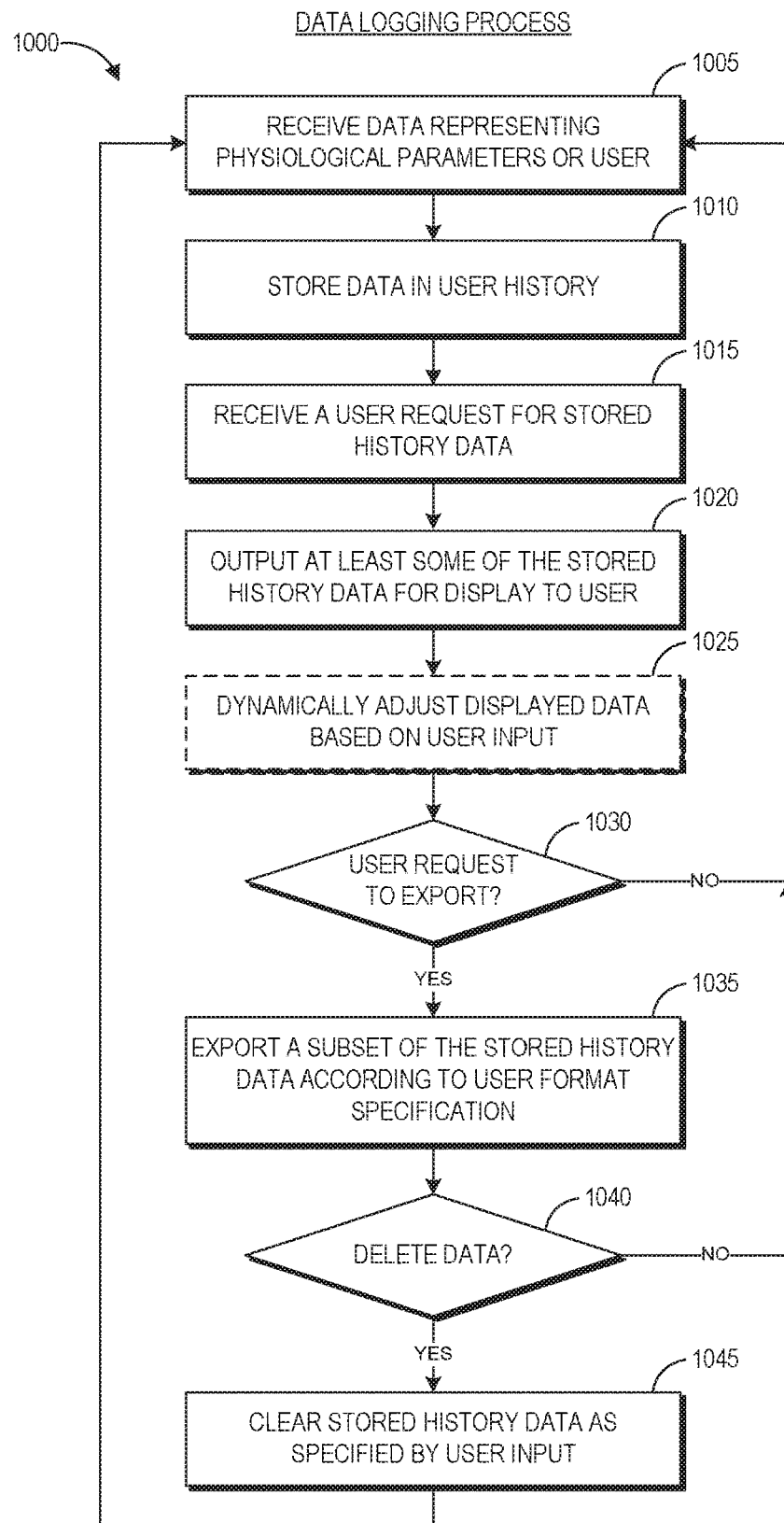


FIG. 10

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PHYSIOLOGICAL MONITOR WITH MOBILE COMPUTING DEVICE CONNECTIVITY

RELATED APPLICATIONS

This application is a continuation of U.S. application Ser. No. 14/033,315, filed Sep. 20, 2013, entitled "PHYSIOLOGICAL MONITOR WITH MOBILE COMPUTING DEVICE CONNECTIVITY," which claims the benefit of U.S. Provisional Application No. 61/703,729 filed Sep. 20, 2012, entitled "Patient Monitor with Mobile Computing Device Connectivity," the disclosures of which are hereby incorporated by reference in their entirety.

BACKGROUND

Field of the Disclosure

The present disclosure relates in general to noninvasive patient monitoring systems, including oximeters and co-oximeters, and their accessories such as sensors or cables. In particular, this disclosure relates to patient monitors capable of connectivity to a mobile computing device.

Description of the Related Art

Oximetry utilizes a noninvasive optical sensor to measure physiological parameters of a patient. In general, the sensor has light emitting diodes (LEDs) that transmit optical radiation into a tissue site and a detector that responds to the intensity of the optical radiation after absorption (e.g., by transmission or reflectance) by, for example, pulsatile arterial blood flowing within the tissue site. Based on this response, a processor determines measurements for oxygen saturation (SpO_2), pulse rate, plethysmograph waveforms, perfusion quality index (e.g., an index that quantifies perfusion), assessments of other blood constituents, parameters or analytes, including for example, a percent value for arterial carbon monoxide saturation (HbCO), a percent value for methemoglobin saturation (a brownish-red form of hemoglobin that cannot function as an oxygen carrier) (HbMet), total hemoglobin (HbT), fractional SpO_2 (SpaO_2) or the like. Additionally, caregivers often desire knowledge of HbO_2 , Hb , blood glucose (HbGu), water, the presence or absence of therapeutic drugs (aspirin, Dapson, nitrates, or the like) or abusive/recreational drugs (methamphetamine, alcohol, steroids, or the like), concentrations of carbon dioxide (CO_2), oxygen (O_2), oxygen concentration, pH levels, bilirubin, perfusion quality, albumin, cyanmethemoglobin, and sulfhemoglobin (HbSulf), signal quality or the like. It is noted that "oximetry" as used herein encompasses its broad ordinary meaning known to one of skill in the art, which includes at least those noninvasive procedures for measuring parameters of circulating blood through spectroscopy. Moreover, "plethysmograph" as used herein (commonly referred to as "photoplethysmograph"), encompasses its broad ordinary meaning known to one of skill in the art, which includes at least data representative of a change in the absorption of particular wavelengths of light as a function of the changes in body tissue resulting from pulsing blood.

Oximeters capable of reading many of the foregoing parameters during noise due to patient movement, electromagnetic interference, and ambient light are available from Masimo Corporation (Masimo) of Irvine, Calif. Moreover, portable and other oximeters are disclosed in at least U.S. Pat. Nos. 6,770,028, 6,658,276, 6,157,850, 6,002,952, and

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5,769,785, incorporated by reference herein, and others patent publications such as those listed at <http://www.masimo.com/patents.htm>. Such noise filtering oximeters have gained rapid acceptance in a wide variety of medical applications, including surgical wards, intensive care and neonatal units, general wards, home care, physical training, and virtually all types of monitoring scenarios. Some blood parameter monitors including oximeters are the standard of care in certain critical environments like surgery and neonatal care.

SUMMARY

Mobility and ease of use are key factors in the health care industry because they correlate to efficient, rapid patient care as well as enable patients to participate in their own care. Therefore, the present disclosure provides physiological monitoring devices which are compatible with handheld monitors such as common mobile computing devices for ease of use and portability.

This disclosure describes embodiments of a mobile physiological sensor that can be conveniently used in conjunction with existing mobile devices of users in a variety of contexts. In certain embodiments, a physiological monitoring system can be designed to include a sensor and cable assembly with a processing board or card, and the system can be connectable to a mobile computing device, such as a smartphone, such that display of the monitored physiological data can occur on the computing device. The board or card can communicate the data for display with the mobile computing device wirelessly or through a physical and electrical connection with the cable assembly. In some embodiments, the board or card can include one or more signal processors and associated memory, I/O, and the like to provide monitored physiological data to applications executing on traditional smartphone processing environments, such that board or card handles advanced signal processing and the smartphone displays parameter data. In an embodiment, the board is housed in a portion of the cable such that it is not directly coupled to the sensor or the smartphone connector. This configuration has the advantage of mechanically isolating the board so that it does not encumber the sensor or the smartphone connection. As a result, the physiological monitoring system can be more portable than existing monitoring systems, thereby facilitating enhanced patient care for more patients.

For example, such a system can be sent home with a patient to gather physiological measurement data outside the hospital setting. In addition, portable physiological monitoring equipment as disclosed herein can facilitate the gathering of physiological measurement data in a variety of other contexts, such as sports or extreme sports, military training and combat, aviation, health awareness, high-altitude activities, monitoring of professionals in dangerous conditions, screening for medical conditions such as congenital heart defects, field hospitals, and mobile medical clinics, to name a few.

Physiological monitoring systems such as are described herein enable oximeter use outside of the traditional hospital setting. This is beneficial for more comprehensive patient care. For instance, prior to a surgical procedure during which a patient will be sedated, such as by general anesthesia, a physician can be concerned about the patient's proclivity toward apnea. A portable oximetry sensor compatible with the patient's smartphone can be sent home with the patient prior to the procedure, and the sensor can be worn overnight. Data collected from the sensor can be passed to the smart-

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phone and made available to the doctor, such as by uploading to the internet or being downloadable from the device, to identify a risk of hypoxemia. This example illustrates one of the many benefits of a portable oximetry system compatible with a common mobile computing device.

For purposes of summarizing the disclosure, certain aspects, advantages and novel features of the inventions have been described herein. It is to be understood that not necessarily all such advantages can be achieved in accordance with any particular embodiment of the inventions disclosed herein. Thus, the inventions disclosed herein can be embodied or carried out in a manner that achieves or optimizes one advantage or group of advantages as taught herein without necessarily achieving other advantages as can be taught or suggested herein.

BRIEF DESCRIPTION OF THE DRAWINGS

Throughout the drawings, reference numbers can be re-used to indicate correspondence between referenced elements. The drawings are provided to illustrate embodiments of the inventions described herein and not to limit the scope thereof.

FIG. 1A illustrates an embodiment of a physiological monitoring system.

FIG. 1B illustrates another embodiment of a physiological monitoring system.

FIG. 1C illustrates an exploded view of one embodiment of the cable components of FIG. 1A.

FIG. 2 illustrates a block diagram of an embodiment of a mobile physiological monitoring system.

FIG. 3 illustrates an embodiment of a computing environment in which a mobile patient monitoring device can communicate with various computing devices and services over a network.

FIGS. 4A-4D illustrate various embodiments of software applications for display and management of physiological monitoring data.

FIGS. 5A-5C illustrate various embodiments of mobile physiological sensors assemblies.

FIG. 6 illustrates an embodiment of a pre-anesthesia monitoring process.

FIG. 7 illustrates an embodiment of a continuum of care process.

FIG. 8 illustrates an embodiment of a mobile physiological data monitoring process.

FIG. 9 illustrates an embodiment of a user-guided monitoring process.

FIG. 10 illustrates an embodiment of a data-logging process.

DETAILED DESCRIPTION

I. Example Mobile Physiological Monitoring Systems

FIGS. 1A, 1B, and 1C illustrate embodiments of a physiological monitoring system 100. The physiological monitoring system 100 shown in FIG. 1A includes a sensor 110, first cable 120, processing module 130, second cable 140, connection port 150, and a mobile computing device, illustrated here as smartphone 160. Although specific reference can be made to smartphones in this disclosure, any mobile computing device compatible with the physiological sensor system can be used. A compatible mobile computing device can be one of a wide range of mobile devices such as a mobile communications device (such as a smartphone),

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laptop, tablet computer, netbook, PDA, media player, mobile game console, wristwatch, wearable computing device, or other microprocessor based device configured to interface with a physiological sensor. Some embodiments of the mobile computing device can be used with the system for display of data and/or storage of data. Cables 120, 140 used with the device can be flex cables or other cables, including cables having triboelectric properties.

As illustrated, the sensor 110 can be a pulse oximeter capable of being secured to a digit such as a finger, for example the Masimo Rainbow® pulse oximeter. However, this is for illustrative purposes only, and the sensor 110 can be any physiological sensor. In some embodiments, other varieties of pulse oximeters can be used, for example adhesive sensors, combination reusable/disposable sensors, soft and/or flexible wrap sensors, infant or pediatric sensors, multisite sensors, or sensors shaped for measurement at a tissue site such as an ear. In other embodiments, the sensor 110 can be any of a variety of sensors, such as a pulse oximeter, a brain function monitor such as an electroencephalograph ("EEG"), a gas monitor such as a capnometer or capnograph, an acoustic respiratory sensor, a heart function monitor such as an electrocardiograph ("ECG"), blood alcohol level sensors, temperature sensors, respiratory inductive plethysmography bands, bioelectric sensors, electronic fetal monitors, or the like. The sensor 110 can be reusable in some embodiments, can be disposable in some embodiments, and in other embodiments the sensor 110 can have both reusable and disposable components. In some embodiments, the sensor can be available in different sizes.

As illustrated in FIG. 1B, in an embodiment, cable 120 can include a port 170 at the sensor-facing end of the cable 120, and a disposable, connectable sensor 180 may be attached to the cable 120. In some embodiments, the connectable sensor 180 can be reusable, or can be partially reusable and partially disposable. A sensor connection mechanism 172 can be configured to receive, or otherwise connect to, connectable sensors of different types, such as any of the physiological sensors discussed above. Although connection port 150 is illustrated as being configured for physical and electrical connection to a mobile device, in some embodiments, the connection port may be a wireless connection port configured to wirelessly transmit filtered physiological parameter data to the mobile device or another computing device.

In various oximeter embodiments, the sensor 110 provides data in the form of an output signal indicative of an amount of attenuation of predetermined wavelengths (ranges of wavelengths) of light by body tissues, such as, for example, a digit, portions of the nose or ear, a foot, or the like. The predetermined wavelengths often correspond to specific physiological parameter data desired, including for example, blood oxygen information such as oxygen content ("SpOC"), oxygen saturation ("SpO₂"), blood glucose, total hemoglobin ("SbHb"), methemoglobin (SbMet"), carboxy-hemoglobin ("SpCO"), bulk tissue property measurements, water content, pH, blood pressure, respiration related information, cardiac information, indications of perfusion ("PI"), pleth variability indices ("PVI"), or the like. In some embodiments, sensor data can provide information regarding physiological parameters such as EEG, ECG, acoustic respiration rate ("RRa"), end-tidal carbon dioxide ("EtCO₂"), return of spontaneous circulation ("ROSC"), or the like.

The sensor data can be corrupted by noise due to patient movement, electromagnetic interference, or ambient light. Therefore, the sensor data is transmitted from sensor 110

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along the first cable **120** to the processing module **130**, which can apply noise filtering and signal processing techniques described below to provide output data for display on the smartphone **160**. Such complex processing techniques can exceed the processing capabilities of the smartphone **160**, and therefore the processing module **130** drives operation of the sensor **110** and handles signal processing and transmits the processed sensor parameter data as output measurement data. Smartphone **160** can be coupled to the processing module **130** by a second cable **140** and connection port **150**, in some embodiments, and in other embodiments can be configured to wirelessly transmit the parameter data to the smartphone **160** or another computing device.

Smartphone **160** can include a display screen such as an LED or LCD screen, and can include touch sensitive technologies in combination with the display screen. Smartphone **160** can include software configured to display some or all of the output measurement data on the display screen. The data display can include numerical or graphical representations of blood oxygen saturation, heart rate, and/or a plethysmographic waveform, and some embodiments can simultaneously display numerical and graphical data representations.

The smartphone **160** can include software such as an application configured to manage output measurement data from the processing module **130**. The application functionality can include trend analysis, current measurement information, alarms associated with above/below threshold readings, reminders to take measurement data at certain times or cycles, display customization, iconic data such as hearts beating, color coordination, bar graphs, gas bars, charts, graphs, or the like, all usable by a caregiver or smartphone user to enable helpful and directed medical monitoring of specified physiological parameters. The smartphone **160** can also include network connection capabilities such as one or more of a cellular network, satellite network, Bluetooth, ZigBee, wireless network connection such as Wi-Fi, and a wired network connection.

In some embodiments, software capable of analyzing the output measurement data received from the processing module **130** and making the data available in an appropriate manner for health management is installed on the smartphone **160**. In some embodiments, the smartphone **160** includes software which allows a user to view the data in a multitude of ways. For example, in some embodiments a user can be able to view the raw data received from the sensor **110**. In other embodiments, a user can be able to select from a plurality of graphical representations of the data (e.g., bar graphs, charts, etc.). In other embodiments, the user can be able to manipulate the data to visualize trends in the data. The smartphone **160** can also be able to alert the user and/or a physician or other care provider to an abnormal data reading. For example, an abnormally low or high blood oxygen saturation reading can cause the smartphone **160** to buzz, vibrate or otherwise notify the user of an abnormal reading, or to transmit a notification to a physician via a network.

The smartphone **160** can have the capability of sending physiological data to a computer (e.g., a home computer) on which the user manages his health data. The data can also be sent to a physician or pharmacist for their expertise and feedback. The smartphone **160** and the computing device to which data is being sent can be connected directly or via a network such as a LAN, WAN or the Internet. The connection can be wired or wireless. Other connection configurations are also possible.

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The system **100** as illustrated in FIG. **1C** shows an exploded view of the processing module **130** and the connection port **150** to reveal the components thereof. The processing module **130** drives operation of the sensor **110** and receives raw detected signals from the sensor **110**. The processing module **130** processes the raw detected signals to determine a physiological measurement. The processing module **130**, in some embodiments, employs advanced signal processing techniques, including parallel engines and adaptive filters, to allow accurate monitoring of arterial oxygen saturation and pulse rate even during the most challenging conditions. In some embodiments, the processing module **130** can employ Signal Extraction Technology, or Masimo SET®, using parallel signal processing engines to separate the arterial signal from sources of noise (including the venous signal) to measure SpO₂ and pulse rate accurately, even during motion. The processing module **130** can filter raw physiological sensor data input from the sensor **110**, and the processing module **130** can provide filtered physiological parameter data to the mobile computing device for display or storage.

One drawback of implementing physiological measurement technology on mobile computing devices is the processing overhead typically required for recognizing parameters from data input by the sensor by filtering such raw physiological measurement data. Processing overhead measures the total amount of work the central processing unit (CPU) of the device can perform and the percentage of that total capacity which is used by individual computing tasks, such as filtering raw physiological measurement data. In total, these tasks must require less than the processor's overall capacity. Moreover, complicated software required to process raw signals and determine physiological measurements can be stored in the processing module **130** in a separate memory unit separate from the mobile device. This frees up memory available to the mobile device.

The current generation of mobile processors is not well adapted to deal with the complexity and corresponding processing overhead of filtering raw physiological measurement data, especially in conjunction with the many other common high performance uses of mobile devices. As an example, the mobile device processor may be used to run a mobile physiological monitoring application concurrently with receiving sensor data, among other applications selected by the user. Many common mobile applications such as maps, games, email clients, web browsers, etc., are typically open on a user's smartphone. During physiological monitoring, a substantially constant stream of data can be sent from the sensor to the mobile device. Accordingly, if the mobile CPU is required to filter the raw data, device performance can be impaired and the user can experience significant latency in the use of other applications. If the data filtering overhead exceeds the overall processing capacity of the CPU then the mobile device would be incapable of processing the data, and the user can experience serious technical problems as a result.

Overload of the CPU can significantly increase system power consumption. To mitigate the possibility of CPU overload, a larger processor can be provided. However, increasing the size of the mobile processor core or cache would deliver performance increases only up to a certain level, beyond which heat dissipation issues would make any further increase in core and cache size impractical. Additionally, overall processing capacity is further limited by the smaller size of many mobile devices, which limits the number of processors that can be included in the device.

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Because mobile computing devices are generally battery-powered, high performance uses also shortens battery life.

By providing a separate processing module **130** to mediate the data flow from the sensor **110** to the mobile device **160**, the complex signal processing required for generating recognizable physiological parameters from raw sensor data can be handled by the processing module **130** and not the mobile CPU. Moving the signal processing calculations away from the mobile CPU frees it up for important core tasks as well as processing of mobile applications. Further, optimizing the mobile CPU can directly correlate with increased battery life, even considering the power draw of the processing module **130** on the mobile device battery. Accordingly, incorporation of a processing module **130** into a mobile sensor cable can be beneficial for conserving processing of the mobile CPU and for reducing battery demands across the system **100**.

Coupled to cable **120** is an information element **133**. The information element **133** could be provided through an active circuit such as a transistor network, memory chip, EEPROM (electronically erasable programmable read-only memory), EPROM (erasable programmable read-only memory), or other identification device, such as multi-contact single wire memory devices or other devices, or the like.

The processing module **130** includes a lower shell **131**, an enclosure with bend relief **132**, processing board **134**, and an upper shell **135**. The enclosure **132**, upper shell **135**, and lower shell **131** surround the processing board **134** and can protect the sensitive circuitry of the board **134** from damage. In such an embodiment, processing board **134** is the portion of the module **130** that communicates with the first cable **120** and sensor **110**, as well as with the second cable **140** and mobile computing device. In an embodiment, the board **134** can access information stored on the information element **133** of the first cable **120**.

In an embodiment, the processing module **130** is located in a middle portion of the cable, away from either the sensor **110** or the connection port **150**. The processing module **130** can be located a first distance from, and mechanically isolated from, the sensor, so as not to interfere with the placement of the sensor on a measurement site of a user's body. This placement prevents the sensor from being encumbered by the processing module **130** and interfering with placement and use of the sensor. Thus, the sensor is also kept relatively lightweight for ease of use. The processing module **130** can be located a first distance from, and mechanically isolated from, the connection port **150**, so as not to interfere with the ability of the connection port **150** to secure to a user's mobile device. This allows the connection port **150** to be unencumbered by the bulk and weight of the processing module **130** which could interfere with the connection to the user's mobile device. In some embodiments, the second distance can be smaller than the first distance, placing the processing module **130** closer to the connection port **150** than to the sensor **110**. This prevents the weight of the processing module **130** from interfering with or pulling on the sensor **110**. In an embodiment, the components of the processing module **130** are constructed from lightweight materials in order to avoid pulling the sensor **110** off of a user or disconnecting the connection port **150** from a mobile device.

The processing module **130** and sensor **110** draw power for operation from the mobile computing device for operation. This frees the processing module **130** from needing a separate power source. Also, although a display screen can be included on the processing module **130**, no separate

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display screen is necessary as the measurements are displayed on the user's mobile device.

The enclosure **132** can have a bend relief portion **138** on either side. The bend relief portions **138** may enhance the electrical and mechanical integrity and overall performance of the cable assembly by providing a gradual transition from the flexible cables to substantially rigid connection points with the processing board **134** contained within the enclosure. The bend relief portions **138** can prevent mechanical force, such as an axial load or flexing, that is applied to the exterior of either cable **120, 140** from being transferred to the electrical terminations with the processing board **134**. The bend relief portions **138** can be premolded and formed with the body of the enclosure, and in some embodiments a crimp ring may be secured around the cable within each bend relief.

The enclosure **132** can be formed, in some embodiments, by a flexible plastic or rubber material. Suitable materials can include thermoplastic rubbers such as Santoprene®. The upper and lower shells **135, 131** can be formed from a hard plastic material. Suitable materials can include thermoplastic polymers. For example, in an embodiment the upper and lower shells **135, 131** can be formed from a blend of two or more of polycarbonate (PC), polyethylene terephthalate (PET), polybutylene terephthalate (PBT), or another polyester, such as Bayer Makroblend® UT5207. In another embodiment, the upper and lower shells **135, 131** can be formed from a resin, for example a blend of semi-crystalline polyester (typically PET or PBT) and PC, such as XENOY™ Resin 6620U. The material for the upper and lower shells **135, 131** can be selected for having desirable impact resistance, toughness, and heat resistance. The upper and lower shells **135, 131** can be formed from the same or different materials.

The body portion of the enclosure **132** can be formed as a gasket which can seal between the upper shell **135** and lower shell **131** and form a substantially water-tight seal, in order to protect the processing board **134** from moisture. In some embodiments, the upper and lower shells **135, 131** can be formed to fit together with the enclosure **132** in a substantially water-tight manner. In an embodiment, the upper and lower shells **135, 131** can be sealed to the enclosure **132** using epoxy around the perimeter of each shell, and/or on mounting posts located on the shell or the enclosure. In some embodiments, the cable entry areas of each bend relief portion **138** of the enclosure **132** can also be filled with epoxy to form a substantially sealed enclosure for the processing board **134**.

The cables **120, 140** can be constructed with a Kevlar fiber core for strength and durability, in some embodiments. The Kevlar fiber core can be bundled in the center of a plurality of signal lines, for example five signal lines. The signal lines can be tinned copper jacketed with polypropylene (PP). The bundle of signal lines can be encased in a braided outer shield, for example a tinned copper outer shield with approximately 95% minimum coverage of the bundled signal lines. The outer shield may be encased, in turn, by a multi-layer Teflon film or wrap, in some embodiments, to form a low-friction separator and barrier from an outer jacket. The cables **120, 140** can be further protected by a medical grade PVC outer jacket, or an outer jacket constructed from another biocompatible, flexible plastic or rubber material. Other configurations for the cables **120, 140** are possible. The cables can be designed to have a minimum pull strength of 75 kg, or approximately 75 kg, in some embodiments.

As illustrated, some embodiments can optionally include a second processing board **136**. For example, the first processing board **134** can be a digital processing board and the second processing board **136** can be an analog processing board. The analog and digital processing boards may perform separate processing functions. In some embodiments, wires from the first cable **120** can be connected to the analog processing board **136**, and wires from the second cable **140** can be connected to the digital processing board **136**. In some embodiments, the digital processing board can be in communication with the first information element **133**. The first information element **133** can be an EPROM or EEPROM device. The analog processing board can be in communication with a second information element **137** coupled to cable **120**. The second information element **127** can be a resistor, in some embodiments, for example an ArCal or ProCal resistor. A resistance value of the resistor can be indicative of a wavelength of light used in an oximetry sensor **110** coupled to the cable **120**, and the resistor can be coupled in parallel with the sensor.

In one embodiment, the processing board or boards can include one of many OEM boards commercially available from Masimo which process incoming intensity signals responsive to an amount of attenuation of light in pulsing patient blood and which determine output measurements for a wide variety of physiological parameters from the processing. The processing board **134** can include the MS-2040 OEM board available from Masimo, which can measure Masimo optical SET measurements such as oxygen saturation (SpO₂), pulse rate, perfusion index (PI), signal quality (SIQ), optionally pleth variability index (PVI), and the like. The physiological monitoring system **100** can also include, in addition to or instead of the MS-2040 OEM board, other processing boards available from Masimo. For example, the physiological monitoring system **100** can include the MX-5 board available from Masimo, which has variable power consumption based on which parameters are being acquired and displayed. The MX-5 board can measure the Masimo SET parameters described above plus optional Rainbow® parameters including: hemoglobin (SpHb), oxygen content (SpOC), carboxyhemoglobin (SpCO), methemoglobin (SpMet), and acoustic respiration rate (RRa) (among possibly others). The addition of the acoustic respiration rate can result in the display of the physiological monitoring system **100** outputting a second waveform (e.g., an acoustic respiration waveform).

The board **134** can include a signal processing system. Embodiments of the signal processing system can employ a noise filtering system configured to filter the data obtained during pulse oximetry measurements using red and infrared light, as such data is often contaminated due to motion. Identification and removal of these motion artifacts is often a prerequisite to any signal processing used to obtain blood oxygen saturation, pulse rate, or other physiological data. The signal processing system can provide the desired parameters as outputs for a display. Outputs for display are, for example, blood oxygen saturation, heart rate, and a clean plethysmographic waveform. Complex operations such as noise filtering and signal processing can require specialized processing or significant computational overhead, such that a typical user mobile device can not have sufficient processing power. Accordingly, the processing module **130** can perform signal processing on raw data received from the sensor and can provide physiological parameters as an output to a display and/or storage device.

The connection port **150** includes shell **151**, bend relief **152**, connector **153**, and cap **154**. Bend relief **152** is an

important feature of a medical cable assembly for both the electrical and mechanical integrity and performance of the second cable **140**. The connection port **150** is typically rigid, and the bend relief **152** provides a transition from the stiffness of the connection port **150** to the flexibility of the second cable **140**. Preferably, bend relief **152** will prevent mechanical force applied to the exterior of the cable from being transferred to the electrical terminations within the connector, which could lead to failure.

Shell **151** generally encloses connector **153** and can be matable with cap **154** to provide added protection for the connector **153**. Connector **153** can be shaped to physically and electrically connect with a specific device. Connection port **150** can be one of many different types of ports. For example, connection port **150** can be a device-specific port such as an iPhone port or another smartphone port, a USB port, an Ethernet port for connection to a wired network, a serial port (e.g., RS232), a video out port which allows projection of the device screen on a larger display, combinations of the same, or the like. Further, the connection port **150** can be equipped with one or more wireless interfaces (such as WiFi, Bluetooth, Zigbee, or the like).

FIG. 2 illustrates a block diagram of an example physiological monitoring system **200**. As illustrated, the system **200** includes a cable **230** and a mobile device **220**. The cable **230** includes a sensor **202**, which can be any of the physiological sensors described above with respect to FIGS. 1A, 1B, and 1C, and a signal processing module **210**. The mobile device **220** can provide power **206** to the signal processing module **210** and the sensor **202**. The sensor **210** can transmit raw data **204** to the signal processing module **210**, and the signal processing module can convert the raw data **204** into data representing physiological parameters **226** for transmission to the mobile device **220**.

The mobile device **220** can be any of the portable computing devices discussed above, such as a smartphone, laptop, tablet, or the like. The mobile device **220** can include a display **222** for display of the parameters, for example in a user interface and/or software application, as discussed in more detail below. The display **222** can include a display screen such as an LED or LCD screen, and can include touch sensitive technologies in combination with the display screen. The mobile device **220** can also include storage **224**, which can be configured for storage of parameters **226** and parameter history data and/or software applications for managing the data and sensor **110**. In some embodiments, the storage **224** can be physical storage of the device **220**, and in some embodiments the storage **224** can be remote storage, such as on a server or servers of a data hosting service. The mobile device **220** can also include a network connectivity feature **228** such as Bluetooth, satellite network capability, mobile communications capability, Wi-Fi, or the like. In some embodiments the mobile device **220** can also include a data transfer port.

The signal processing module **210** can be configured to receive raw sensor data **204** from the sensor **202**, and to process the raw data **204** into identifiable parameters **226** for display and/or storage by the mobile device **220**. In some embodiments, the mobile device **220** can not have sufficient processing power to handle the conversion of raw data **204** to identifiable parameters **226**. For example, in the context of pulse oximetry, the signal processing module **210** can use adaptive filter technology to separate an arterial signal, detected by a pulse oximeter sensor, from the non-arterial noise (e.g. venous blood movement during motion). During routine patient motions (shivering, waving, tapping, etc.), the resulting noise can be quite substantial and can easily

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overwhelm a conventional ratio based oximetry system. This can provide accurate blood oxygenation measurements even during patient motion, low perfusion, intense ambient light, and electrocautery interference. Accordingly, false alarms can be substantially eliminated without sacrificing true alarms.

The signal processing module **210** can include a noise filter engine **212**. In some embodiments, the noise filter engine **212** can perform a discrete saturation transform process to substantially remove noise from the raw sensor data **204**. The discrete saturation transform process outputs a maximum power as an SpO₂ percentage. For example, the discrete saturation transform process can build a noise reference signal from incoming red and infrared signals of a pulse oximeter sensor, in some embodiments, for each percent SpO₂, from 1 to 100 percent. The noise reference signal can be passed through an adaptive filter which can cancel correlated frequencies between the reference signal and the incoming infrared signal. If the frequencies between the two inputs are all similar, the entire signal can be canceled, and a low energy output occurs. If the frequencies between the two inputs are dissimilar, a minimal amount of signal cancels and a high-energy output can be obtained. The energy output from the adaptive filter can be measured and plotted for all possible saturations from 1 to 100 percent, for example in 0.5 percent increments every 0.4 seconds, in some embodiments. During measurements in which the user exhibits no motion, a discrete cosine transfer algorithm can generate one energy output peak, and several output peaks can be generated during motion. Because arterial blood has the highest oxygen saturation, a peak picker process can select the highest saturation peak as the percent SpO₂.

In some embodiments, the noise filter engine **212** can employ a plurality of adaptive filter processes in parallel to separate the physiological signal from the noise, and can leverage the unique strengths of each adaptive filter processes to obtain accurate readings through various patient conditions. For example, in one embodiment of pulse oximetry measurements, parallel adaptive filters can include a discrete saturation transform, sinusoidal saturation transform, and fast saturation transform, as well as possibly others. A sinusoidal saturation transform can be a time domain transform that defines a window around a derived pulse rate estimate, subtracts a preselected set of frequencies to find a minima, and can use the minima to determine the location of the maximum power and thus the true pulse rate. A fast saturation transform may include, in some embodiments, a spectral or Fourier transform, a spectral analysis, and identification of physiological parameters through frequency, magnitude, or other aspects of the spectral analysis. In one embodiment, demodulation and decimation of the raw sensor data **204** may occur prior to the fast saturation transform.

The noise filter engine **212** can optionally include an arbitration module **214** in embodiments where multiple calculation engines are used. In some embodiments, the arbitration module **214** may be a confidence-based arbitrator. The arbitration module **214** can include instructions to compare the output of each adaptive filter process in order to generate a final determination of the denoised physiological signal. The arbitration module **214** can also arbitrate physiological measurements based on any number of parameters, for example a highest confidence level or whether a threshold confidence level was reached. Furthermore, the arbitration module **214** can arbitrate based on expected values, previous values, averages or the like. Post processor **216** can apply additional signal conditioning techniques to

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the output of the arbitration module **214** in order to output parameter data **226** to the mobile device **220**.

II. Example Computing Environment

FIG. 3 illustrates an embodiment of a computing environment **300** in which a mobile patient monitoring device **330** can communicate with various computing devices and services over a network **305**. Although various devices and services are illustrated, in some embodiments the mobile patient monitoring device **330** can be configured to communicate with a subset of the illustrated devices and services, and in some embodiments can be configured to communicate with only one of the illustrated devices and services.

In an embodiment, the mobile patient monitoring device **330** can communicate over a network **305** with calibration service **310** over the network **305**. The example network **305** shown can be a local area network (LAN), wide area network (WAN), the Internet, an intranet, cellular communications network, satellite communications network, or combinations of the same or the like. The calibration service **310** can accumulate and aggregate received physiological measurement data as calibration data **314** to generate more accurate parameter values. Calibration data for physiological sensors such as pulse oximeters is typically calculated over a patient sample from a clinical study. The clinically generated calibration data can be supplemented, in some embodiments, by the calibration data **314** gathered from physiological sensors **330**. Advantageously, gathering measurement data from a number of mobile physiological sensors **330** can expand such a data set significantly and lead to higher accuracies and/or new discoveries regarding parameter measurement. The calibration data **314** can be stored anonymously or in other manners which are compliant with privacy laws regarding medical data. In some embodiments, non-identifying demographic information can advantageously be associated with the calibration data **314**.

The calibration service **310** can include a calibration module **312** configured with instructions to calculate a best fit function for the population data **316** within the calibration data **314**. The best fit function can be used to generate a calibration curve associating sensor reading values with parameter values. The best fit function can be transmitted to connected patient devices **330** in order to associate sensor readings with more accurate parameter values. Specifically, false positives can be reduced, variances in SpO₂ can be detected and filtered, and/or measurement confidence can be evaluated, among other advantages. Calibration data **314** can also include individual data **318**, for example individual variations from the expected sensor reading to parameter value relationship defined by the best fit function. Methods of using a single sensor to improve calibration data which can be implemented by the disclosed systems are disclosed in U.S. patent application Ser. No. 13/733,782, titled "AUTOMATED CCHD SCREENING AND DETECTION," filed Jan. 3, 2013, the entirety of which is hereby incorporated by reference.

In an embodiment, the mobile patient monitoring devices **330** can communicate with home/mobile clinician devices **320** over the network **305**. Any type of clinician computing device **330** can communicate with mobile patient monitoring device **330** including, for example, laptops, desktops, servers, work stations, tablets, wireless handheld devices such as cell phones, smart phones, personal digital assistants and wireless pagers, combinations of the same or the like. Alternatively or additionally, the mobile patient monitoring

devices **330** can communicate with patient databases of hospitals and other care facilities **225** over the network **305**. The mobile patient monitoring device **330** can output parameter data, trend data and/or alarms to the home/mobile clinician devices **320** and/or hospitals and other care facilities **225**.

III. Example Software Applications

FIGS. **4A-4D** illustrate various embodiments of applications for display and management of physiological monitoring data. Such applications can be available for download or installation on a user device from a provider of the physiological sensors described herein, for example from the provider's web site, or through a mobile store application. In an embodiment, a mobile physiological monitoring software application can be initialized when a user connects a sensor cable to their mobile device. The user interface examples illustrated in FIGS. **4A-4D** are provided to illustrate and not to limit the capabilities of such applications.

Some embodiments of the software application can be used with the smartphone **160** of FIGS. **1A**, **1B**, and **1C**, though any mobile user device can be used in other embodiments. As illustrated in FIG. **4A**, smartphone **160** includes a display **410**, which can be used to generate a user interface for the software application. The application can include a plurality of display portions in which a plurality of physiological parameters can be displayed, such as SpO₂ display **420**, heart rate display **430**, perfusion index display **450**, or plethysmographic waveform display **450**. Any combination of the physiological parameters disclosed herein can be displayed on the smartphone **160**. The configuration of these various display portions is meant for illustrative purposes, and one skilled in the art would appreciate that the parameter displays could be rearranged relative to one another, displayed alone, or the user interface could be modified to include other parameter display portions. Another example of a variety of display portions is illustrated in FIG. **4B**. Further, although some of the parameter display portions employ numerical representations of the physiological data, some embodiments can employ graphical representations, for example a beating heart can indicate heart rate.

The user interface can also include an options display portion **460** which allows the user to interact with his physiological monitoring data in a variety of ways. For example, the user can choose to view trends in the data, as illustrated in FIG. **4C**, or to change the manner in which the data is represented such as by viewing a histogram or other graph. The user can be also able to view the history of his physiological measurement data. In some embodiments, history or trend data can be displayed with a start date and/or time and an end date and/or time, and the user can be able to adjust the window of data displayed. For example, on a touch sensitive interface the user can narrow or expand a window of trend data using a pinch gesture with two fingers. The user can also be able to export a selected amount of trend or history data, such as by electronic mail, through a medical service, or as a spreadsheet, to name a few examples. A settings option can be displayed which would allow the user to modify other aspects of the program, and can also enable the user to set alarms or reminders to take future measurements.

Turning to FIG. **4D**, an example instruction user interface is shown which can be presented to a user upon initialization of the application. The instruction interface can include graphical and numbered steps to guide the user through set

up of the sensor, and can include a user selectable option to start tracking physiological parameter measurements.

In certain embodiments, the application can be downloadable from a computer network at a cost, by subscription, pay-per-use, or the like. Other embodiments can advantageously incorporate caregiver-specific applications which include reminders for timed measurements or protocols. For example, a caregiver for a pre-surgical patient can desire measurement data for a certain minimum time per minimum period (20 min per every hour) or the like to have sufficient data to make diagnosis or decisions for treatment. A caregiver-specific application can be advantageously programmed to accomplish such a protocol. Moreover, signal quality or confidence indicators such as perfusion index ("PI") or signal IQ ("SIQ") can be used to ensure data meets certain minimum confidence and/or signal-to-noise limitations. Thus, the application can implement the protocol and extend or add measurement intervals to ensure minimum signal quality standards are met. Other caregiver-specific applications can provide animated or textual instructions, links to online information regarding certain monitoring situations, ailments, or other useful patient research.

In an embodiment, data acquired through the application can be uploaded to caregiver or device provider systems to increase the population data and used to improve signal processing. In a preferred embodiment, issues of privacy and compliance with governmental regulations are strictly enforced through the application logic. In some embodiments, non-identifying demographic information can advantageously be associated with such data. Moreover, password and/or additional authentication requirements can be required to access stored data in the application, such as, for example, fingerprint technologies, facial recognition technologies employing the smartphone's camera, voice recognition technologies employing the smartphone's audio transducer, or the like can further assist in meeting privacy concerns.

IV. Overview of Compatible Sensor Embodiments

As illustrated in FIG. **5A**, a physiological sensor **520** can be an electroencephalograph ("EEG") configured for measurement of electrical activity along the scalp. Such mobile EEG systems can be used, for example, in detecting and monitoring epileptic activity. EEG systems can also be used for diagnosis and management of sleep disorders or for studies of sleep. Electroencephalography is used extensively in neuroscience, cognitive science, cognitive psychology, neurolinguistics and psychophysiological research. In many of these contexts, a sensor **520** compatible with a common mobile computing device of a user would provide advantages such as convenience and affordability. In some embodiments, the sensor **520** can be SEDLine®, available from Masimo. SEDLine® brain function monitoring can use four channels of information, in some embodiments, to monitor both sides of the brain's electrical activity.

Turning to FIG. **5B**, a capnometer or capnograph **530** can be configured for mobile physiological parameter measurement. Such sensors **530** can be designed for the measurement of CO₂, N₂O, and anesthetic agents, among others. Capnography can be useful for metabolic measurements and nutritional assessment, and accordingly a mobile sensor **530** can provide increased accessibility for such uses.

An acoustic respiratory monitor **540**, as shown in FIG. **5C**, can also be configured for mobile physiological parameter measurement. An acoustic respiratory monitor **540** can measure respiration rate using an adhesive sensor with an

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integrated acoustic transducer that can be comfortably applied to the patient's neck. Continuous monitoring of respiration rate can be important for post-surgical patients receiving patient-controlled analgesia for pain management, as the sedation can induce respiratory depression and place patients at considerable risk of serious injury or death. Accordingly, a mobile respiratory monitor **540** can be desirable for convenient and continuous monitoring of such patients, among other reasons.

V. Overview of Example Mobile Physiological Monitoring Processes

FIG. 6 illustrates an embodiment of a pre-anesthesia monitoring process **600**. The process can be implemented by the physiological monitoring system **100** of FIGS. 1A, 1B, and 1C, in some embodiments.

The process **600** can begin at block **605** in which a care provider recommends a medical procedure requiring anesthesia for a patient. Certain medical conditions can present safety concerns for the patient during anesthesia, so at block **610** the patient can be provided with a portable monitoring system including a sensor connectable to one of the patient's personal mobile computing devices. In some embodiments the patient can be provided with multiple sensors and/or a software application for collection and management of physiological data.

At block **615**, the portable monitoring system can collect and store physiological data from the patient. Optionally, at block **620**, the collected data is analyzed for risk factors indicating a medical condition with implications for anesthesia, such as obstructive sleep apnea. At block **625**, the collected data and/or analysis of the data is provided to the patient's physician or another care provider. In some embodiments, a physician can conduct the analysis after receiving the patient's data.

At decision block **630**, a determination is made regarding whether the data analysis indicates that sleep apnea or another medical condition impacting the safety of anesthesia is present. If such a condition is present in the data, then the process **600** moves to block **645** in which the anesthesiologist is alerted. At step **650**, a patient treatment strategy is developed that addresses the possible complications of the patient undergoing anesthesia with the detected condition. If no safety-impairing medical condition is present in the data, then the process **600** moves to block **640** in which the patient's physician can elect to proceed with the recommended medical procedure and anesthesia.

FIG. 7 illustrates an embodiment of a continuum of care process **700**. The process **700** can be implemented, in some embodiments, by the computing environment **300** of FIG. 3. In an embodiment, the process **600** can be implemented at least in part by the network **305** to facilitate continued patient monitoring when a patient leaves a hospital or other facility.

At block **705**, monitoring data of a patient is received at a clinical facility, for example by a networked medical service which can receive and store patient monitoring data, among other features. Once the patient is discharged, at block **710** the patient can be outfitted with a portable monitoring system. The portable monitoring system can monitor the same parameters as a device used to monitor the patient in the clinical facility. In addition, the portable monitoring system may, for instance, be any of the sensors and processing cable components, or variations thereof, described herein.

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When a patient is discharged, there is a typically a period of time where the patient is not being monitored once the patient leaves the facility. However, the continuum of care process **700** employing mobile physiological sensors can facilitate continued monitoring of the patient, for example during travel between the facility and the patient's residence or when the patient arrives at home, by receiving monitoring data from the patient via a cellular or satellite network at block **715**. An activity level of the patient, for example resting or walking, can be monitored at block **620** in order to set the appropriate thresholds for determining when physiological parameters indicating an alarm condition are occurring at block **725**. The patient's activity level can be monitored by the device, in some embodiments, or can be input by the patient or a care giver.

Periodically, the mobile physiological sensor system can recheck the patient's activity level at block **730** to determine whether the activity level has changed. If the patient's activity level has changed, then the process **700** loops back to block **725** to adjust alarm settings for the patient's physiological data based on the activity level. If the patient's activity level has not changed, then the process **700** can move to block **735** in which it is determined whether an alarm condition is occurring based on the patient's physiological parameters and the alarm settings. A software application installed on the patient's mobile device can be configured to detect the alarm condition. If an alarm condition is not occurring, then the process **700** loops back to block **715** in which the mobile physiological sensor continues to perform physiological measurements and transmit the measurements to the mobile device through a signal conditioning processor. If an alarm condition is detected at block **735**, then the patient's mobile device can pass a notification to a care provider via a network connection. Accordingly, the mobile physiological sensor system can facilitate a continuum of care for a patient and continuous monitoring even when a patient has left a clinical facility.

FIG. 8 illustrates an embodiment of a mobile physiological data monitoring process **800**. The process can be implemented, in some embodiments, by the physiological monitoring system **100** of FIGS. 1A, 1B, and 1C, or the physiological monitoring system **200** of FIG. 2.

At block **805**, a portable user monitoring system is provided including physiological sensor, processing module, and device connection port. The physiological sensor can be any of the sensor examples discussed herein. The processing module can be the processing module **130** described in FIGS. 1A, 1B, and 1C or the signal processing module **210** of FIG. 2. The processing module can implement Masimo SET technology, in some embodiments. The device connection port can be configured for use with a standard personal computing device, such as a smartphone, and can be connected to the processing module physically via a cable or wirelessly.

At block **810**, the user's mobile computing device, while connected to the portable patient monitoring system, provides power to the sensor and processing module. Accordingly, the sensor and processing module can be configured in some embodiments so as to draw only minimal power from the mobile computing device, as such devices are typically powered by batteries.

At block **815**, the processing module receives raw physiological sensor data from the sensor. The processing module performs signal conditioning on the raw data at block **820**, for example any of the signal conditioning techniques described herein, to remove noise from the raw data and obtain physiological parameter data. At block **825**, the

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processing module outputs the physiological parameter data to the user's mobile computing device for display and/or storage on the device. Accordingly, a user can conveniently conduct physiological measurements and be presented with physiological data on their mobile device in a wide variety of contexts.

FIG. 9 illustrates an embodiment of a user-guided monitoring process 900, which can be carried out by a user on their personal computing device without the need for physician or caregiver aid. The process 900 can be carried out by a mobile physiological monitoring application, as discussed above, in conjunction with a mobile physiological sensor. The physiological sensor can be any of the sensor examples discussed herein.

At block 905, the user is instructed to insert the connection port of a cable including a physiological sensor and a processor into a corresponding port on their mobile computing device, and at block 910 the user is instructed to place the sensor at a measurement site. In some embodiments, these blocks can be implemented by an instruction user interface such as is depicted in FIG. 4D and discussed above.

At block 915, the mobile device receives measurement data, which can be raw sensor data that has been processed by a processing module prior to being sent to the mobile device. At block 920, the mobile physiological monitoring application can determine based on the measurement data whether an error is occurring. If it is determined that an error is not occurring, then the mobile device can continue to receive measurement data at block 915. If it is determined that an error is occurring, then the mobile physiological monitoring application can determine a potential or likely error source at block 925.

Based on the determined error source, the mobile physiological monitoring application may, at block 930, display a message to aid the user to aid in resolution of the error. Example messages include "Ensure cable is connected," "Sensor not working," "Place sensor on properly," "Searching for pulse," "Interference detected, see manual," "Low perfusion, see manual," "Too much surrounding light," "Low signal quality, see manual," and "Connecting, please wait," among others. In some embodiments an audible or visual indication can also be provided to alert the user to the presence of the error. At block 935, the mobile physiological monitoring application can determine whether the user has resolved the error. The mobile physiological monitoring application can repeat this action at predetermined intervals until the error is resolved or the application is terminated by the user, in some embodiments. In other embodiments, the mobile physiological monitoring application can determine whether the error has been resolved based on a change in received measurement data values. If, after a predetermined threshold of time, the error is not resolved, then the process 900 ends. If the error is resolved, the process 900 loops back to block 915, and the mobile device can continue to receive measurement data.

FIG. 10 illustrates an embodiment of a data-logging process 1000. The data-logging process 1000 can run continuously or periodically during operation of a mobile physiological monitoring application, as discussed above.

At block 1005, the mobile physiological monitoring application can receive measurement data, which can be raw sensor data that has been processed by a processing module prior to being sent to a mobile device. This data is stored, at block 101, in a user history, for example in storage of the mobile device or in a networked data storage service. At block 1015, the mobile physiological monitoring application determines that a user has requested to be presented with

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history data, and accordingly outputs at least some of the stored data for display to the user at block 1020. In some embodiments, the user can specify a desired range of stored history data when making the request. In other embodiments, the device can output a predetermined range of the history data, for example based on a recent time window of the data or patterns in the data.

At block 1025, the mobile physiological monitoring application can dynamically adjust the amount of displayed data based on user input. This step can be optional based on whether a user provides input regarding adjusting the data. In some embodiments, the user can be able to specify particular physiological parameters to add or remove from the display. In an embodiment implemented on a touch-sensitive display, a user can use a two-finger pinching gesture to change the range of the time window of the data, or can use a swiping motion to move forwards or backwards through the data. Such adjustments can be implemented using other user interface elements on non-touch sensitive displays. A user can also be able to select from a variety of possible representations of the data, such as a chart, graph, plot, or other graphical representation as well as numerical representations such as spreadsheets, in some embodiments.

At block 1030, the mobile physiological monitoring application can receive a user request to export the stored history data. If no such request is received, then the mobile physiological monitoring application can loop back to block 1005 and continue to receive physiological measurement data. If the user requests to export the data, then at block 1035 the mobile physiological monitoring application can export a subset of the stored history data according to user format specification. For example, the user can specify a time and/or date range of data to export, can select a format (such as a spreadsheet or a graph), and can select an exporting means such as email or direct transmission to a physician or networked medical service.

At block 1040, the user can be presented with an option to delete the stored history data. In some embodiments, the user can be asked whether to delete data that has been exported. If the user does not want to delete the data, then the mobile physiological monitoring application can loop back to block 1005 and continue to receive physiological measurement data. If the user requests to delete the data, then the mobile physiological monitoring application can clear stored history data according to user instructions, and can then loop back to block 1005 and continue to receive physiological measurement data.

VI. Terminology

Although many of the examples discussed herein are in the context of pulse oximetry, this is for illustrative purposes only. The sensors, signal conditioning techniques, and mobile applications discussed herein can be adapted for other physiological parameters or for multiple physiological parameters.

Many other variations than those described herein will be apparent from this disclosure. For example, depending on the embodiment, certain acts, events, or functions of any of the algorithms described herein can be performed in a different sequence, can be added, merged, or left out all together (e.g., not all described acts or events are necessary for the practice of the algorithms). Moreover, in certain embodiments, acts or events can be performed concurrently, e.g., through multi-threaded processing, interrupt processing, or multiple processors or processor cores or on other parallel architectures, rather than sequentially. In addition,

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different tasks or processes can be performed by different machines and/or computing systems that can function together.

The various illustrative logical blocks, modules, and algorithm steps described in connection with the embodiments disclosed herein can be implemented as electronic hardware, computer software, or combinations of both. To clearly illustrate this interchangeability of hardware and software, various illustrative components, blocks, modules, and steps have been described above generally in terms of their functionality. Whether such functionality is implemented as hardware or software depends upon the particular application and design constraints imposed on the overall system. The described functionality can be implemented in varying ways for each particular application, but such implementation decisions should not be interpreted as causing a departure from the scope of the disclosure.

The various illustrative logical blocks and modules described in connection with the embodiments disclosed herein can be implemented or performed by a machine, such as a general purpose processor, a digital signal processor (DSP), an application specific integrated circuit (ASIC), a field programmable gate array (FPGA) or other programmable logic device, discrete gate or transistor logic, discrete hardware components, or any combination thereof designed to perform the functions described herein. A general purpose processor can be a microprocessor, but in the alternative, the processor can be a controller, microcontroller, or state machine, combinations of the same, or the like. A processor can also be implemented as a combination of computing devices, e.g., a combination of a DSP and a microprocessor, a plurality of microprocessors, one or more microprocessors in conjunction with a DSP core, or any other such configuration. Although described herein primarily with respect to digital technology, a processor can also include primarily analog components. For example, any of the signal processing algorithms described herein can be implemented in analog circuitry. A computing environment can include any type of computer system, including, but not limited to, a computer system based on a microprocessor, a mainframe computer, a digital signal processor, a portable computing device, a personal organizer, a device controller, and a computational engine within an appliance, to name a few.

The steps of a method, process, or algorithm described in connection with the embodiments disclosed herein can be embodied directly in hardware, in a software module executed by a processor, or in a combination of the two. A software module can reside in RAM memory, flash memory, ROM memory, EPROM memory, EEPROM memory, registers, hard disk, a removable disk, a CD-ROM, or any other form of non-transitory computer-readable storage medium, media, or physical computer storage known in the art. An exemplary storage medium can be coupled to the processor such that the processor can read information from, and write information to, the storage medium. In the alternative, the storage medium can be integral to the processor. The processor and the storage medium can reside in an ASIC. The ASIC can reside in a user terminal. In the alternative, the processor and the storage medium can reside as discrete components in a user terminal.

Conditional language used herein, such as, among others, “can,” “might,” “may,” “e.g.,” and the like, unless specifically stated otherwise, or otherwise understood within the context as used, is generally intended to convey that certain embodiments include, while other embodiments do not include, certain features, elements and/or states. Thus, such conditional language is not generally intended to imply that

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features, elements and/or states are in any way required for one or more embodiments or that one or more embodiments necessarily include logic for deciding, with or without author input or prompting, whether these features, elements and/or states are included or are to be performed in any particular embodiment. The terms “comprising,” “including,” “having,” and the like are synonymous and are used inclusively, in an open-ended fashion, and do not exclude additional elements, features, acts, operations, and so forth. Also, the term “or” is used in its inclusive sense (and not in its exclusive sense) so that when used, for example, to connect a list of elements, the term “or” means one, some, or all of the elements in the list.

While the above detailed description has shown, described, and pointed out novel features as applied to various embodiments, it will be understood that various omissions, substitutions, and changes in the form and details of the devices or algorithms illustrated can be made without departing from the spirit of the disclosure. As will be recognized, certain embodiments of the inventions described herein can be embodied within a form that does not provide all of the features and benefits set forth herein, as some features can be used or practiced separately from others.

What is claimed is:

1. A mobile pulse oximetry system for informing a user of mobile measurement of oxygen saturation (“SpO2”), the mobile pulse oximetry system comprising:

an SpO2 measurement system including:

an optical sensor configured to output one or more signals responsive to light from a light source attenuated by tissue of the user at a measurement site, said one or more signals responsive to an oxygen saturation of said tissue; and

a processing board in data communication with the optical sensor and a mobile computing device including a display and cellular communication, wherein the processing board is configured to:

receive said one or more signals from the optical sensor;

process said one or more signals to generate SpO2 measurement values; and

output the SpO2 measurement values to the mobile computing device; and

one or more hardware processors of the mobile computing device configured to execute an application, the application configured to execute commands to:

generate a graphical user interface having a plurality of display portions;

display, in at least one portion of the plurality of display portions, a representation of a physiological parameter of a plurality of physiological parameters comprising at least the SpO2 measurement values; and

display, in a different portion of the plurality of display portions, a plurality of user inputs configured to allow the user to interact with at least one of the plurality of display portions or the application;

wherein the processing of the one or more signals to generate SpO2 measurement values is performed only on the processing board, thereby freeing up memory available to the mobile computing device; and

wherein the processing board is configured to draw power for operation from the mobile computing device.

2. The mobile pulse oximetry system of claim 1, wherein the application is configured to execute commands to: perform a trend analysis on received SpO2 measurement values; and

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display results of the trend analysis in at least one portion of the plurality of display portions.

3. The mobile pulse oximetry system of claim 2, wherein the display is touch-sensitive, and wherein the application is configured to execute commands to narrow or expand the displayed results of the trend analysis in response to the user using a pinch gesture.

4. The mobile pulse oximetry system of claim 1, wherein the application is configured to execute commands to set reminders to take future measurements.

5. The mobile pulse oximetry system of claim 1, wherein the application is configured to execute commands to output one or more alarms associated with SpO2 measurement values that are above or below threshold SpO2 measurement values.

6. The mobile pulse oximetry system of claim 1, wherein the application is configured to execute commands to output one or more reminders to use the optical sensor to take measurements of SpO2 measurement values at predetermined times or cycles.

7. The mobile pulse oximetry system of claim 1, wherein the application is configured to execute commands to update the representation of the physiological parameter to comprise one or more of a plurality of graphical representations of the SpO2 measurement values, the plurality of graphical representations comprising at least one of bar graphs or charts.

8. The mobile pulse oximetry system of claim 1, wherein the application is configured to execute commands to output an alert, via a network to a designated physician or other care provider, regarding abnormal SpO2 readings.

9. The mobile pulse oximetry system of claim 1, wherein the mobile computing device comprises a smartphone.

10. The mobile pulse oximetry system of claim 1, wherein the mobile computing device comprises a wearable computing device.

11. The mobile pulse oximetry system of claim 1, wherein the mobile computing device comprises a wristwatch.

12. The mobile pulse oximetry system of claim 1, wherein the SpO2 measurement system is configured to wirelessly transmit the SpO2 measurement values to the mobile computing device.

13. A computer-implemented method of informing a user of mobile measurement of oxygen saturation ("SpO2"), the computer-implemented method comprising:

outputting, from an optical sensor of an SpO2 measurement system, one or more signals responsive to light from a light source attenuated by tissue of the user at a measurement site, said one or more signals responsive to an oxygen saturation of said tissue; and

via a processing board of the SpO2 measurement system, the processing board in data communication with the optical sensor and a mobile computing device including a display:

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receiving said one or more signals from the optical sensor;

processing said one or more signals to generate the SpO2 measurement values; and

outputting the SpO2 measurement values to the mobile computing device; and

via an application configured to execute commands on the mobile computing device:

generating a graphical user interface having a plurality of display portions;

displaying, in at least one portion of the plurality of display portions, a representation of a physiological parameter of a plurality of physiological parameters comprising at least the SpO2 measurement values; and

displaying, in a different portion of the plurality of portions, a plurality of user inputs configured to allow the user to interact with at least one of the plurality of display portions or the application.

14. The computer-implemented method of claim 13, further comprising, via the application:

performing a trend analysis on received SpO2 measurement values; and

displaying results of the trend analysis in at least one portion of the plurality of display portions.

15. The computer-implemented method of claim 13, further comprising, via the application, outputting one or more alarms associated with SpO2 measurement values that are above or below threshold SpO2 measurement values.

16. The computer-implemented method of claim 13, further comprising, via the application, outputting one or more reminders to use the optical sensor to take measurements of SpO2 measurement values at predetermined times or cycles.

17. The computer-implemented method of claim 13, further comprising, via the application, updating the representation of the physiological parameter to comprise one or more of a plurality of graphical representations of the SpO2 measurement values, the plurality of graphical representations comprising at least one of bar graphs or charts.

18. The computer-implemented method of claim 13, further comprising, via the application, outputting an alert, via a network to a designated physician or other care provider, regarding abnormal SpO2 readings.

19. The computer-implemented method of claim 13, further comprising wirelessly transmitting the SpO2 measurement values from the SpO2 measurement system to the mobile computing device.

20. The computer-implemented method of claim 13, further comprising, via the application, enabling the user to set reminders to take future measurements.

* * * * *

EXHIBIT 9



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EXAMINER	
FARDANESH, MARJAN	

ART UNIT	PAPER NUMBER
3791	

NOTIFICATION DATE	DELIVERY MODE
05/31/2019	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

efiling@knobbe.com

jayna.cartee@knobbe.com

Office Action Summary**Application No.**

15/880,071

Applicant(s)

Muhsin et al.

Examiner

MARJAN FARDANESH

Art Unit

3791

AIA (FITF) Status

No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status1) ☐ Responsive to communication(s) filed on ____.☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on ____.2a) ☐ This action is **FINAL**.2b) ☒ This action is non-final.3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.**Disposition of Claims***5) ☐ Claim(s) ____ is/are pending in the application.

5a) Of the above claim(s) ____ is/are withdrawn from consideration.

6) ☐ Claim(s) ____ is/are allowed.7) ☒ Claim(s) 2-21 is/are rejected.8) ☐ Claim(s) ____ is/are objected to.9) ☐ Claim(s) ____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers10) ☐ The specification is objected to by the Examiner.11) ☒ The drawing(s) filed on 01/25/2018 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 11912) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).**Certified copies:**a) ☐ All b) ☐ Some** c) ☐ None of the:1. ☐ Certified copies of the priority documents have been received.2. ☐ Certified copies of the priority documents have been received in Application No. ____.3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)1) ☒ Notice of References Cited (PTO-892)3) ☐ Interview Summary (PTO-413)

Paper No(s)/Mail Date ____.

2) ☒ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)4) ☐ Other: ____.Paper No(s)/Mail Date 09/20/2018.

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DETAILED ACTION

Notice of Pre-AIA or AIA Status

1. The present application is being examined under the pre-AIA first to invent provisions.

Status of Claims

2. Claim(s) 2-21 is/are currently under examination.

Priority

3. Applicant's claim for the benefit of priority under 35 U.S.C. 119(e) to provisional application(s), 61/703, 729 filed 09/20/2012, is acknowledged.
4. Applicant's claim for the benefit of priority to continuation application(s), 14/033,315 filed 09/20/2013, is acknowledged.

Information Disclosure Statement

5. The information disclosure statement (IDS) document(s) submitted on 09/20/2018 is/are in compliance with the provisions of 37 C.F.R. 1.97. Accordingly, the IDS document(s) have been fully considered by the examiner.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112(a):

(a) IN GENERAL.—The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.

The following is a quotation of the first paragraph of pre-AIA 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly

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connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. The following is a quotation of 35 U.S.C. 112(b):

(b) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

The following is a quotation of 35 U.S.C. 112 (pre-AIA), second paragraph:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 11-12 are rejected under 35 U.S.C. 112(a) or 35 U.S.C. 112 (pre-AIA), first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor or a joint inventor, or for pre-AIA the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 11-12, disclose that the mobile pulse oximetry system of claim 2 further comprises wearable device comprising a wristwatch. However, According to Applicant's disclosure the mobile computing device can be a smartphone or wristwatch or wearable device (PGPub version [0023]). Applicant's specification does not support the mobile pulse oximetry system of claim 2 comprising a sensor, processing board and a mobile computing device does not further include a wearable device comprising a wristwatch. Therefore, the broader limitations claimed (a system comprising both a mobile computing device (claim 1) and a separate wearable computing device (claim 11) or wristwatch (claim 12)) is not supported by more specific Applicant's disclosure (the mobile computing device can be a smartphone or wristwatch or wearable device). Applicant should amend claim 11 to recite "The mobile pulse oximetry system of claim 2, wherein the mobile computing device is a wearable computing device". Applicant should amend claim 12 to recite "The mobile pulse

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oximetry system of claim 2, wherein the wearable computing device comprises a wristwatch”.

9. Claim 12 rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor, or for pre-AIA the applicant regards as the invention.

Claim **12** recites the limitation "the wearable computing device" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of pre-AIA 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claim(s) 2, 6, 9, 13-14, 16, 19-20 is/are rejected under pre-AIA 35 U.S.C. 102(b) as being anticipated by Lisogurski (USPN 2011/0077473).

Regarding claim 2, Lisogurski teaches a mobile pulse oximetry system for informing a user of mobile measurement of oxygen saturation (“SpO2”), the mobile pulse oximetry system comprising: an SpO2 measurement system including: an optical sensor configured to output one or more signals responsive to light from a light source attenuated by tissue of a patient at a measurement site, said one or more signals responsive to an oxygen saturation of said tissue (element 14 figure 2, [0025]); and a processing board

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(element 20 figures 2-3) in data communication with the optical sensor and a mobile computing device (element 12 figures 2-3) including a display (figure 1), wherein the processing board is configured to: receive the said one or more signals from the optical sensor, process said the one or more signals to generate SpO2 measurement values, and output the SpO2 measurement values to the mobile computing device ([0046]-[0047]); and an application configured to execute its commands on the mobile computing device, wherein the application is configured to cause display of a representation of the SpO2 measurement values on the display ([0022], [0052]).

Regarding claim 6, Lisogurski teaches the application is configured to execute its commands to cause the mobile computing device to cause output of alarms associated with SpO2 measurement values that are above or below threshold SpO2 measurement values ([0048]).

Regarding claim 9, Lisogurski teaches the application is configured to execute its commands to cause the mobile computing device to output an alert, via a network to a designated physician or other care provider, regarding abnormal SpO2 readings ([0048]).

Regarding claim 13, Lisogurski teaches the SpO2 measurement system is configured to wirelessly transmit the SpO2 measurement values to the mobile computing device (figure 10, [0055]).

Regarding claim 14, Lisogurski teaches a computer-implemented method of informing a user of mobile measurement of oxygen saturation ("SpO2"), the computer-implemented method comprising: outputting, from an optical sensor of an SpO2 measurement system, one or more signals responsive to light from a light source

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attenuated by tissue of a patient at a measurement site, said one or more signals responsive to an oxygen saturation of said tissue (element 14 figure 2, [0025]); and via a processing board of the SpO2 measurement system, the processing board (element 20 figures 2-3) in data communication with the optical sensor and a mobile computing device (element 12 figures 2-3) including a display (figure 1); receiving the said one or more signals from the optical sensor ([0046]-[0047]); processing said the one or more signals to generate the SpO2 measurement values ([0046]-[0047]); and outputting the SpO2 measurement values to the mobile computing device ([0046]-[0047]); and via an application configured to execute its commands on the mobile computing device, causing display of a representation of the SpO2 measurement values on the display ([0022], [0052]).

Regarding claim 16, Lisogurski teaches via the application, causing the mobile computing device to cause output of alarms associated with SpO2 measurement values that are above or below threshold SpO2 measurement values ([0048]).

Regarding claim 19, Lisogurski teaches via the application, causing the mobile computing device to output an alert, via a network to a designated physician or other care provider, regarding abnormal SpO2 readings ([0048]).

Regarding claim 20, Lisogurski teaches wirelessly transmitting the SpO2 measurement values from the SpO2 measurement system to the mobile computing device (figure 10, [0055]).

Claim Rejections - 35 USC § 103

12. The following is a quotation of pre-AIA 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 3-5, 7-8, 10, 15, 17-18, 21 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Lisogurski (USPN 2011/0077473) as applied to claim 2 above, and further in view of Lamego et al. (USPN 2012/0226117).

Regarding claims 3, 15, Lisogurski fails to disclose that the application is configured to execute its commands to cause the mobile computing device to perform trend analysis on received SpO2 measurement values and to display results of the trend analysis on the display. Lamego et al. discloses an application within smartphone that performs trend analysis ([0100]). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to have modified the monitor of Lisogurski to incorporate trend analysis on the display, with a reasonable expectation of success, because the prior art teaches application that obtains data and displays data, as taught by Lisogurski, and since performing trend analysis on the data obtained would have been known in the art, as taught by Lamego et al.. The rationale would have been to enable helpful and directed medical monitoring of specified physiological parameters, in addition to the predictable use of prior art elements according to their established functions. KSR, 550, U.S. at 417.

Lisogurski fails to teach that the display is touch sensitive and the application is configured to execute its commands to cause the mobile computing device to narrow or expand a window of trend data in response to the user using a pinch gesture. Lamego et al. discloses that the screen supports gestures such as an x/y swipe inertia scroll,

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presshold, 2 point pinch zoom, 3 point pinch zoom and swiping ([0107]), and the trend line timeframe, or displayed time period, may be configurable through, for example, a pinch or dual finger parting to respectively shorten or lengthen the time period ([0079]).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention of invention to have modified the display as taught by Lisogurski to incorporate the feature to narrow or expand a window of trend data in response to the user using a pinch gesture, with a reasonable expectation of success, because the prior art teaches displaying measurements, as taught by Lisogurski, and since narrow or expand a window of trend data in response to the user using a pinch gesture would have been known in the art, as taught by Lamego et al.. The rationale would have been to enable helpful and directed medical monitoring of specified physiological parameters, in addition to the predictable use of prior art elements according to their established functions. KSR, 550, U.S. at 417.

Regarding claims 5, 21, Lisogurski fails to disclose that the application is configured to execute its commands to cause the mobile computing device to enable a user to set reminders to take future measurements. Lamego et al. discloses an application within smartphone that allows users to set reminders to take measurements at certain times or cycles ([0100]). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to have modified the monitor as taught by Lisogurski to output reminders to use to take measurements at predetermined times or cycles, with a reasonable expectation of success, because the prior art teaches monitor receiving measurements from the sensor, as taught by Lisogurski, and since setting reminders to take measurements at certain times would have been known in the art, as

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taught by Lamego et al.. The rationale would have been to enable helpful and directed medical monitoring of specified physiological parameters, in addition to the predictable use of prior art elements according to their established functions. KSR, 550, U.S. at 417.

Regarding claims 7, 17, Lisogurski fails to disclose that the application is configured to execute its commands to cause the mobile computing device to cause output of reminders to use the pulse oximeter to take measurements of SpO2 measurement values at predetermined times or cycles. Lamego et al. discloses an application within smartphone that allows users to set reminders to take measurements at certain times or cycles ([0100]). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to have modified the monitor as taught by Lisogurski to output reminders to use to take measurements at predetermined times or cycles, with a reasonable expectation of success, because the prior art teaches monitor receiving measurements from the sensor, as taught by Lisogurski, and since setting reminders to take measurements at certain times would have been known in the art, as taught by Lamego et al.. The rationale would have been to enable helpful and directed medical monitoring of specified physiological parameters, in addition to the predictable use of prior art elements according to their established functions. KSR, 550, U.S. at 417.

Regarding claims 8, 18 Lisogurski fails to disclose that the application is configured to execute its commands to cause the mobile computing device to provide functionality to a user to select from a plurality of graphical representations of the SpO2 measurement values including bar graphs and charts. Lamego et al.

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discloses an application within smartphone that allows users to select bars and charts ([0078], [0100]). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to have modified the monitor as taught by Lisogurski to select from plurality of bar graphs and charts, with a reasonable expectation of success, because the prior art teaches monitor receiving measurements from the sensor and displaying the measurements, as taught by Lisogurski, and since displaying measurements in bar graphs and charts and allowing the user to select them would have been known in the art, as taught by Lamego et al.. The rationale would have been to enable helpful and directed medical monitoring of specified physiological parameters, in addition to the predictable use of prior art elements according to their established functions. KSR, 550, U.S. at 417.

Regarding claim 10, Lisogurski fails to disclose that the monitor (mobile computing device) is a smartphone. Lamego et al. discloses that the sensor 104 send data to the smartphone ([0089], [0099]-[0100], figure 1). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to have utilized smart phone as thought by Lamego et al. instead of the monitor disclosed by Lisogurski, with a reasonable expectation of success, because the prior art teaches monitor including processor and display, as taught by Lisogurski, and since smart phone including processor and display would have been known in the art, as taught by Lamego et al.. The rationale would have been to enable helpful and directed medical monitoring of specified physiological parameters, in addition to the predictable use of prior art elements according to their established functions. KSR, 550, U.S. at 417.

Application/Control Number: 15/880,071
Art Unit: 3791

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14. Claims 11-12 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Lisogurski (USPN 2011/0077473) as applied to claim 2 above, and further in view of Banet et al. (USPN 2010/0160798).

Regarding claims 11-12, Lisogurski fails to disclose a wearable computing device comprising a wristwatch. Banet et al. discloses wrist worn transceiver 272 (figure 25) including a display for displaying vital signs, wrist strap that affixes the transceiver to the patient's wrist like a conventional wristwatch, a flexible cable that connects the transceiver to a pulse oximeter probe ([0146]). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to have incorporated the wristwatch transceiver of Banet et al. into the device of Lisogurski, with a reasonable expectation of success, because the prior art teaches connecting oximeter sensor to a computing device for displaying measurements, as taught by Lisogurski, and since connecting the oximeter to a wrist worn transceiver for displaying the measurements would have been known in the art, as taught by Banet et al.. The rationale would have been to enable helpful and directed medical monitoring of specified physiological parameters, in addition to the predictable use of prior art elements according to their established functions. KSR, 550, U.S. at 417.

Conclusion

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARJAN FARDANESH whose telephone number is (571)270-5508. The examiner can normally be reached on Monday-Friday 9:00-17:00.

Application/Control Number: 15/880,071
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Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at <http://www.uspto.gov/interviewpractice>.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Mallari can be reached on (571)272-4729. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MARJAN FARDANESH/
Examiner, Art Unit 3791

<i>Notice of References Cited</i>	Application/Control No. 15/880,071		Applicant(s)/Patent Under Reexamination Muhsin et al.	
	Examiner MARJAN FARDANESH		Art Unit 3791	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
*	A	US-20110077473-A1	03-2011	Lisogurski; Daniel	A61B5/14551	600/301
*	B	US-20120226117-A1	09-2012	Lamego; Marcelo M.	A61B5/14532	600/316
*	C	US-20100160798-A1	06-2010	BANET; Matt	A61B5/02125	600/490
	D					
	E					
	F					
	G					
	H					
	I					
	J					
	K					
	L					
	M					

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	CPC Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

MAS.925C1

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Inventor	:	Bilal Muhsin
App. No.	:	15/880071
Filed	:	January 25, 2018
For	:	PHYSIOLOGICAL MONITOR WITH MOBILE COMPUTING DEVICE CONNECTIVITY
Examiner	:	Fardanesh, Marjan
Art Unit	:	3791
Conf. No.	:	4417

RESPONSE TO OFFICE ACTION DATED MAY 31, 2019

Mail Stop Amendment

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Commissioner:

In response to the Office Action dated May 31, 2019 in the above-referenced application, Applicant respectfully submits the following:

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Remarks/Arguments begin on page 7 of this paper.

Application No.: 15/880071
Filing Date: January 25, 2018

AMENDMENTS TO THE CLAIMS

Please amend the claims as indicated below.

1. (Canceled)
2. (Currently Amended) A mobile pulse oximetry system for informing a user of mobile measurement of oxygen saturation (“SpO2”), the mobile pulse oximetry system comprising:

an SpO2 measurement system including:

an optical sensor configured to output one or more signals responsive to light from a light source attenuated by tissue of a patient at a measurement site, said one or more signals responsive to an oxygen saturation of said tissue; and

a processing board in data communication with the optical sensor and a mobile computing device including a display and cellular communication, wherein the processing board is configured to:

receive the said one or more signals from the optical sensor,

process the ~~said the~~ one or more signals to generate SpO2 measurement values, and

output the SpO2 measurement values to the mobile computing device; and

an application configured to ~~execute~~ be installed ~~its commands~~ on the mobile computing device, wherein the application is configured to cause display of a representation of the SpO2 measurement values on the display, the display comprising:

a plurality of display portions, each display portion configured to display a representation of a physiological parameter of a plurality of physiological parameters comprising at least the SpO2 measurement values; and

an options display portion comprising a plurality of user inputs configured to allow the user to interact with at least one of: the plurality of display portions or the application,

wherein the processing of the one or more signals to generate SpO2 measurement values is performed only on the processing board, thereby freeing up memory available to the mobile computing device, and

Application No.: 15/880071
Filing Date: January 25, 2018

wherein the processing board is configured to draw power for operation from the mobile computing device.

3. (Previously Presented) The mobile pulse oximetry system of claim 2, wherein the application is configured to execute its commands to cause the mobile computing device to perform trend analysis on received SpO2 measurement values and to display results of the trend analysis on the display.

4. (Previously Presented) The mobile pulse oximetry system of claim 3, wherein the display is touch-sensitive, and wherein the application is configured to execute its commands to cause the mobile computing device to narrow or expand a window of trend data in response to the user using a pinch gesture.

5. (Previously Presented) The mobile pulse oximetry system of claim 2, wherein the application is configured to execute its commands to cause the mobile computing device to enable a user to set reminders to take future measurements.

6. (Previously Presented) The mobile pulse oximetry system of claim 2, wherein the application is configured to execute its commands to cause the mobile computing device to cause output of alarms associated with SpO2 measurement values that are above or below threshold SpO2 measurement values.

7. (Previously Presented) The mobile pulse oximetry system of claim 2, wherein the application is configured to execute its commands to cause the mobile computing device to cause output of reminders to use the pulse oximeter to take measurements of SpO2 measurement values at predetermined times or cycles.

8. (Previously Presented) The mobile pulse oximetry system of claim 2, wherein the application is configured to execute its commands to cause the mobile computing device to provide functionality to a user to select from a plurality of graphical representations of the SpO2 measurement values including bar graphs and charts.

9. (Previously Presented) The mobile pulse oximetry system of claim 2, wherein the application is configured to execute its commands to cause the mobile computing device to output an alert, via a network to a designated physician or other care provider, regarding abnormal SpO2 readings.

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10. (Previously Presented) The mobile pulse oximetry system of claim 2, wherein the mobile computing device is a smartphone, and wherein the application is adapted to run on the smartphone.

11. **(Currently Amended)** The mobile pulse oximetry system of claim 2, ~~further comprising~~ wherein the mobile computing device comprises a wearable computing device.

12. **(Currently Amended)** The mobile pulse oximetry system of claim 2, wherein the ~~wearable~~ mobile computing device comprises a wristwatch.

13. (Previously Presented) The mobile pulse oximetry system of claim 2, wherein the SpO2 measurement system is configured to wirelessly transmit the SpO2 measurement values to the mobile computing device.

14. **(Currently Amended)** A computer-implemented method of informing a user of mobile measurement of oxygen saturation (“SpO2”), the computer-implemented method comprising:

outputting, from an optical sensor of an SpO2 measurement system, one or more signals responsive to light from a light source attenuated by tissue of a patient at a measurement site, said one or more signals responsive to an oxygen saturation of said tissue; and

via a processing board of the SpO2 measurement system, the processing ~~board~~ in data communication with the optical sensor and a mobile computing device including a display:

receiving the said one or more signals from the optical sensor;

processing said the one or more signals to generate the SpO2 measurement values; and

outputting the SpO2 measurement values to the mobile computing device;

and

via an application configured to execute its commands on the mobile computing device, causing display of a representation of the SpO2 measurement values on the display, the display comprising:

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a plurality of display portions, each display portion configured to display a representation of a physiological parameter of a plurality of physiological parameters comprising at least the SpO2 measurement values; and

an options display portion comprising a plurality of user inputs configured to allow the user to interact with at least one of the plurality of display portions or the application.

(Previously Presented) The computer-implemented method of claim 14, further comprising, via the application:

causing the mobile computing device to perform trend analysis on received SpO2 measurement values; and

causing the mobile computing device to display results of the trend analysis on the display.

15. (Previously Presented) The computer-implemented method of claim 14, further comprising, via the application, causing the mobile computing device to cause output of alarms associated with SpO2 measurement values that are above or below threshold SpO2 measurement values.

16. (Previously Presented) The computer-implemented method of claim 14, further comprising, via the application, causing the mobile computing device to cause output of reminders to use the pulse oximeter to take measurements of SpO2 measurement values at predetermined times or cycles.

17. (Previously Presented) The computer-implemented method of claim 14, further comprising, via the application, causing the mobile computing device to provide functionality to a user to select from a plurality of graphical representations of the SpO2 measurement values including bar graphs and charts.

18. (Previously Presented) The computer-implemented method of claim 14, further comprising, via the application, causing the mobile computing device to output an alert, via a network to a designated physician or other care provider, regarding abnormal SpO2 readings.

19. (Previously Presented) The computer-implemented method of claim 14, further comprising wirelessly transmitting the SpO2 measurement values from the SpO2 measurement system to the mobile computing device.

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Filing Date: January 25, 2018

20. (Previously Presented) The computer-implemented method of claim 14, further comprising, via the application, enabling a user to set reminders to take future measurements.

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Filing Date: January 25, 2018

REMARKS

In response to the Office Action, Applicant respectfully requests that the Examiner reconsider the above-captioned application in view of the foregoing amendments and the following remarks.

Previously, Claims 2-21 were pending. By this response, Claims 2, 11, 12 and 14 have been amended. Accordingly, Claims 2-21 are pending for consideration.

Rejection of Claims 11-12 under 35 USC § 112(a)

The Office Action rejected Claims 11-12 as allegedly failing to comply with the written description requirement. Applicant respectfully disagrees. However, in the interest of advancing prosecution has amended Claims 11 and 12 as indicated above. Accordingly, Applicant respectfully requests withdrawal of the rejections of Claims 11 and 12 under 35 U.S.C. § 112(a).

Claims 2, 6, 9, 13-14, 16, and 19-20 are not anticipated under 35 USC § 102

The Office Action rejected Claims 2, 6, 9, 13-14, 16, and 19-20 as being allegedly anticipated under 35 USC § 102(b) by U.S. Patent Publication No. 2011/0077473 (“Lisogurski”). Applicant respectfully disagrees. However, in the interest of advancing prosecution, Applicant has amended independent Claims 2 and 14.

Claim 2 has been amended to recite, in part:

“the display comprising:

a plurality of display portions, each display portion configured to display a representation of a physiological parameter of a plurality of physiological parameters comprising at least the SpO2 measurement values; and

an options display portion comprising a plurality of user inputs configured to allow the user to interact with at least one of the plurality of display portions or the application,

wherein the processing of the one or more signals to generate SpO2 measurement values is performed only on the processing board, thereby freeing up memory available to the mobile computing device, and

wherein the processing board is configured to draw power for operation from the mobile computing device.”

Support for the amendments can be found in at least paragraphs [0061]-[0062] and FIGS. 4A-4D of the application as originally filed.

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Filing Date: January 25, 2018

Applicant respectfully submits that the Office Action has not shown Lisogurski discloses, teaches, or suggests at least the above quoted features of Claim 2.

Claim 14 has been amended to recite in part:

“the display comprising:

a plurality of display portions, each display portion configured to display a representation of a physiological parameter of a plurality of physiological parameters comprising at least the SpO2 measurement values; and

an options display portion comprising a plurality of user inputs configured to allow the user to interact with at least one of the plurality of display portions or the application.”

For at least reasons similar to those discussed above for Claim 2, Applicant respectfully submits that the Office Action has not shown that cited references disclose, teach, or suggest at least the above-quoted features of Claim 14.

Thus, for at least the foregoing reasons, Applicant respectfully submits that the Office Action has not shown that Lisogurski or the other cited references (alone or in any combination) anticipate, teach, or suggest at least the above-quoted features of Claims 2 and 14. Accordingly, Applicant requests that the rejection of Claims 2 and 14 under 35 U.S.C. § 102 be withdrawn.

Dependent Claims 6, 9, 13, 16, and 19-20

Applicant respectfully submits that each of dependent Claims 6, 9, 13, 16, and 19-20 is separately patentable at least in view of each claim’s dependency from a patentable independent claim and in further view of additional features recited in each claim.

For at least these reasons, Applicant respectfully requests withdrawal of the rejection of each of Claims 6, 9, 13, 16, and 19-20.

Claims 3-5, 7-8, 10, 15, 17-18, and 21 are not obvious under 35 USC § 103(a)

The Office Action has rejected Claims 3-5, 7-9, 10, 15, 17-18, and 21 under 35 USC § 103(a) as being allegedly unpatentable over Lisogurski as applied to Claim 2 in view of U.S. Publication No. 2012/0226117 (“Lamego”). Claims 11-12 are rejected under 35 USC § 103(a) as being allegedly unpatentable over Lisogurski as applied to Claim 2 in view of U.S. Publication No. 2010/0160798 (“Banet”).

Application No.: 15/880071
Filing Date: January 25, 2018

Applicant respectfully submits that each of dependent 3-5, 7-9, 10, 15, 17-18, and 21 is separately patentable at least in view of each claim's dependency from a patentable independent claim and in further view of additional features recited in each claim.

For at least these reasons, Applicant respectfully requests withdrawal of the rejection of each of Claims 3-5, 7-9, 10, 15, 17-18, and 21.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicant is not conceding in this application that previously pending claims are not patentable. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: September 30, 2019

By: /Harnik Shukla/ _____
Harnik Shukla
Registration No. 73,097
Registered Practitioner
Customer No. 64735
(949) 721-5278

Docket No.: MAS.925C1

Customer No. 64735

INFORMATION DISCLOSURE STATEMENT

First Inventor	: Bilal Muhsin
App. No.	: 15/880071
Filed	: January 25, 2018
For	: PHYSIOLOGICAL MONITOR WITH MOBILE COMPUTING DEVICE CONNECTIVITY
Examiner	: Fardanesh, Marjan
Art Unit	: 3791
Conf. No.	: 4417

Mail Stop Amendment

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

References and Listing

Pursuant to 37 CFR 1.56, an Information Disclosure Statement listing references is provided herewith. Copies of any listed foreign and non-patent literature references are being submitted.

No Disclaimers

To the extent that anything in the Information Disclosure Statement or the listed references could be construed as a disclaimer of any subject matter supported by the present application, Applicant hereby rescinds and retracts such disclaimer.

Timing of Disclosure

This Information Disclosure Statement is being filed after receipt of a First Office Action, but before the mailing date of a Final Action and before the mailing date of a Notice of Allowance.

This Statement is accompanied by the fees set forth in 37 CFR 1.17(p). The Commissioner is hereby authorized to charge any additional fees which may be required or to credit any overpayment to Account No. 11-1410.

Application No.: 15/880071

Filing Date: January 25, 2018

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: September 30, 2019

By: /Harnik Shukla/ _____
Harnik Shukla
Registration No. 73,097
Registered Practitioner
Customer No. 64735
(949) 721-5278

31422815

EXHIBIT 10



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/033,315	09/20/2013	Bilal Muhsin	MASIMO.925A	9323
64735 7590 08/13/2015 KNOBBE, MARTENS, OLSON & BEAR, LLP 2040 MAIN STREET FOURTEENTH FLOOR IRVINE, CA 92614			EXAMINER LEE, YOOJIN	
			ART UNIT 3777	PAPER NUMBER
			NOTIFICATION DATE 08/13/2015	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jayna.cartee@knobbe.com
efiling@knobbe.com

Office Action SummaryApplication No.
14/033,315Applicant(s)
MUHSIN ET AL.Examiner
YOOJIN LEEArt Unit
3777AIA (First Inventor to File)
Status
No**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --****Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09/20/2013.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

- 5) ☒ Claim(s) 1-21 is/are pending in the application.
 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 1-21 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

- 10) ☒ The specification is objected to by the Examiner.
- 11) ☒ The drawing(s) filed on 09/20/2013 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

- a) ☐ All b) ☐ Some** c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)
 Paper No(s)/Mail Date ____.
- 3) ☐ Interview Summary (PTO-413)
 Paper No(s)/Mail Date ____.
- 4) ☐ Other: ____.

Application/Control Number: 14/033,315
Art Unit: 3777

Page 2

DETAILED ACTION

Notice of Pre-AIA or AIA Status

1. The present application is being examined under the pre-AIA first to invent provisions.

Specification

2. The disclosure is objected to because of the following informalities:
 - In paragraph [0006], line 12, “board is house in a portion” should read “board is housed in a portion”
 - In paragraph [0008], line 1, “such as are described herein” should read “such as those that are described herein”

Appropriate correction is required.

Claim Interpretations - 35 USC § 112

The following is a quotation of 35 U.S.C. 112(f):

(f) Element in Claim for a Combination. – An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

The following is a quotation of pre-AIA 35 U.S.C. 112, sixth paragraph:

An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

3. Claim limitations “sensor configured to monitor,” “port configured to be connectable to the mobile computing device,” and “network communication module configured to transmit data” has/have been interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, because it uses/they use a generic placeholder “sensor,” “port,” and “module” coupled with functional language “to monitor,” “to be connectable to,” and “to transmit” without reciting

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sufficient structure to achieve the function. Furthermore, the generic placeholder is not preceded by a structural modifier.

Since the claim limitation(s) invokes 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, claim(s) 1, 2, and 8 has/have been interpreted to cover the corresponding structure described in the specification that achieves the claimed function, and equivalents thereof.

If applicant wishes to provide further explanation or dispute the examiner's interpretation of the corresponding structure, applicant must identify the corresponding structure with reference to the specification by page and line number, and to the drawing, if any, by reference characters in response to this Office action.

If applicant does not intend to have the claim limitation(s) treated under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, applicant may amend the claim(s) so that it/they will clearly not invoke 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, or present a sufficient showing that the claim recites/recite sufficient structure, material, or acts for performing the claimed function to preclude application of 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph.

For more information, see MPEP § 2173 *et seq.* and *Supplementary Examination Guidelines for Determining Compliance With 35 U.S.C. 112 and for Treatment of Related Issues in Patent Applications*, 76 FR 7162, 7167 (Feb. 9, 2011).

Claim Rejections - 35 USC § 101

4. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Application/Control Number: 14/033,315
Art Unit: 3777

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Claims 10-21 are rejected under 35 U.S.C. 101 because the claimed invention is directed to a judicial exception (i.e., a law of nature, a natural phenomenon, or an abstract idea) without significantly more.

Claim(s) 10-21 is/are directed to a method for mobile physiological monitoring. In this case, the claimed invention relies upon providing a physiological monitoring system, generating a physiological signal, processing/filtering the signal, and transmitting filtered data to a mobile device, which are all considered an abstract idea, or concepts similar to those found by the courts to be abstract, as it involves generating, processing, and transmitting signals, which are mathematically relating data (prong 1 of the two-part test). With regards to the additional steps appended to the abstract idea (prong 2 of the two-part test), these steps/elements amount to no more than: insignificant post-solution activity and/or data gathering (e.g. outputting filtered raw data, tracking and displaying filtered data, outputting stored history data, connecting to a network, transmitting data over network, generating a calibration curve); routine and conventional data processing steps (e.g. determining a noise signal, filtering raw data to remove noise signal, transmitting filtered data, incorporating filtered data into a calibration data set to generate calibration curve); and/or conventional elements of a computing environment (e.g. sensor, cable including a processing board, mobile computing device, wireless communication module, mobile monitoring application, display, network). As discussed in Mayo, simply appending conventional steps, specified at a high level of generality, "to a method already "well known in the art" is not "enough" to supply the "inventive concept" needed to transform the abstract idea into a patent-eligible invention.

Additionally, the claims fail to recite any limitations that purport to improve the functioning of the computer itself or effect an improvement in any other technology or technical

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field, or provide meaningful limitations beyond generally linking the use of an abstract idea to a particular technological environment.

Viewed as a whole, these additional claim element(s) do not provide meaningful limitation(s) to transform the abstract idea into a patent eligible application of the abstract idea such that the claim(s) amounts to significantly more than the abstract idea itself.

Additionally, the claimed invention also fails to recite any specific machine for performing the apparent computational steps, which also weighs against eligibility. Applicant is reminded, however, that generic computer implementation is not the sort of “additional feature” that provides any “practical assurance that the process is more than a drafting effort designed to monopolize the [abstract idea] itself.” *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U. S., Pp. 11–14.

For additional guidance, applicant is directed generally to MPEP 2106 and to the USPTO’s June 2014 Preliminary Examination Instructions in view of *Alice v. CLS Bank*, published online at: http://www.uspto.gov/patents/announce/interim_alice_guidance.jsp. This two-part analysis supersedes MPEP 2106(II)(A) and 2106(II)(B). Applicant should note that if the claimed invention reads on both eligible and non-eligible subject matter, a rejection under 35 U.S.C. 101 is necessitated over the non-eligible subject matter.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of pre-AIA 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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6. Claims 1-2, 4, 6-7, 9-10, and 12-14 are rejected under pre-AIA 35 U.S.C. 102(b) as being anticipated by Lisogurski (US 2011/0077473 A1).

Regarding claim 1, Lisogurski teaches a physiological monitoring system comprising a sensor configured to monitor one or more physiological parameters of a patient (14 in Fig. 1); a mobile computing device (12 in Fig. 1) comprising a display (16 in Fig. 1); and a cable including a processing board (20 in Fig. 1 and Paragraph 0040) configured to establish an electrical signal connection between the sensor and the mobile computing device, wherein the processing board receives raw data representing the monitored one or more physiological parameters and performs signal processing to provide filtered parameter data to the mobile computing device (Paragraph 0047).

Regarding claim 2, Lisogurski teaches the physiological monitoring system of claim 1, wherein the sensor is coupled to the processing board using a first portion of the cable (18 and 22 in Fig. 1), and wherein the processing board is coupled to a port (30 in Fig. 1) using a second portion of the cable (26 and 28 in Fig. 1), the port configured to be connectable to the mobile computing device (12 in Fig. 1).

Regarding claim 4, Lisogurski teaches the physiological monitoring system of claim 1, wherein the processing board (56 in Fig.3) is in communication with an information element (48 in Fig. 3 and Paragraphs 0036 and 0038).

Regarding claim 6, Lisogurski teaches the physiological monitoring system of claim 1, wherein the mobile computing device presents the filtered data to a user on the display (Paragraph 0047).

Regarding claim 7, Lisogurski teaches the physiological monitoring system of claim 1, wherein the mobile computing device further comprises storage configured to store the filtered parameter data (Paragraph 0038).

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Regarding claim 9, Lisogurski teaches the physiological monitoring system of claim 1, wherein the sensor comprises one or more of a pulse oximeter, capnometer, capnograph, acoustic respiratory sensor, electroencephalograph, electrocardiograph, or temperature sensor (Paragraph 0021).

Regarding claim 10, Lisogurski teaches a computer-implemented method of mobile physiological monitoring, the method comprising providing a portable physiological monitoring system comprising a sensor configured to monitor one or more physiological parameters of a patient (14 in Fig. 1), and a cable including a processing board (20 in Fig. 1 and Paragraph 0040) configured to establish an electrical connection between the sensor and a mobile computing device (Paragraph 0040); generating raw data representing the monitored one or more physiological parameters using the sensor (Paragraph 0046); receiving the raw data at the processing board (Paragraph 0047); performing signal processing on the raw data using the processing board, wherein the signal processing generates filtered parameter data (Paragraph 0047); and transmitting the filtered parameter data to the mobile computing device (Paragraph 0047).

Regarding claim 12, Lisogurski teaches the computer-implemented method of claim 10, wherein the filtered parameter data comprises pulse rate or oxygen saturation (Paragraph 0047).

Regarding claim 13, Lisogurski teaches the computer-implemented method of claim 10, wherein transmitting the filtered parameter data to the mobile computing device comprises transmitting the filtered parameter data through the cable (20 in Fig. 1) and a connection port (30 in Fig. 1) to the mobile computing device (Paragraph 0047 and Fig. 6).

Regarding claim 14, Lisogurski teaches the computer-implemented method of claim 10, wherein transmitting the filtered parameter data to the mobile computing device comprises transmitting the filtered parameter data through the cable to a wireless communication module

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(120 in Fig. 10), wherein the filtered parameter data is transmitted wirelessly to the mobile computing device from the wireless communication module (Paragraph 0055 and Fig. 10).

Claim Rejections - 35 USC § 103

7. The following is a quotation of pre-AIA 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claim 3 is rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Lisogurski (US 2011/0077473 A1) in view of Turicchia (US 2010/0198094 A1).

Regarding claim 3, Lisogurski teaches the physiological monitoring system of claim 1, but does not explicitly teach wherein the processing board comprises both a digital processing board and an analog processing board. However, Turicchia teaches a wearable monitoring system, wherein the processing board comprises both a digital processing board and an analog processing board (Turicchia; Paragraph 0043). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide the system of Lisogurski with an analog processor and a digital processor in order to receive and process physiological signals from monitoring sensors, and to trigger a visual or audible alarm in the event that a patient requires medical attention.

Claim 5 is rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Lisogurski (US 2011/0077473 A1) in view of Al-Ali (US 2011/0071370 A1).

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Regarding claim 5, Lisogurski teaches the physiological monitoring system of claim 1, but does not explicitly teach wherein the mobile computing device provides a power signal to the processing board and the sensor. Al-Ali, however, teaches a sensor module (Al-Ali; Fig. 6) wherein an external device provides a power signal to the processing board and the sensor (Al-Ali; Paragraph 0026). Although Al-Ali does not explicitly teach a mobile computing device providing a power signal to the processing board and the sensor, it is conventional to connect a sensor via cable to a mobile computing device, i.e. monitor, in order to provide power to the sensor during operation. Also, incorporating portable batteries to a physiological sensor could be disadvantageous because the battery-life becomes significantly shorter and the sensor could stop taking measurements after a certain period of time. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide the system of Lisogurski with a mobile computing device that provides a power signal to the processing board and the sensor in order to increase battery-life and to make sure the patient is continuously monitored even over a period of days.

Claims 8 and 15-18 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Lisogurski (US 2011/0077473 A1) in view of Swedlow (US 2006/0224059 A1).

Regarding claim 8, Lisogurski teaches the physiological monitoring system of claim 1, but does not explicitly teach a network communication module configured to transmit the filtered parameter data to at least one of a calibration service, a physician computing device, or a medical facility patient database. Swedlow, however, teaches an oximeter system comprising a network communication module configured to transmit the filtered parameter data to a medical facility patient database (Swedlow; Paragraphs 0028-0029). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide the system

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of Lisogurski with a network communication module, as taught by Swedlow, in order to easily transmit stored patient information whenever a patient needs to be transferred to a different room in a hospital or a different medical facility.

Regarding claim 15, the combination of Lisogurski and Swedlow teaches the computer-implemented method of claim 10, further comprising providing a mobile monitoring application, i.e. memory chip, configured to track and display the filtered parameter data (Swedlow; Paragraph 0025). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide the method of Lisogurski with a mobile monitoring application, as taught by Swedlow, in order to monitor a trend in a patient's physiological condition in order to observe any health improvements or deterioration for diagnostic or therapeutic purposes.

Regarding claim 16, the combination of Lisogurski and Swedlow teaches the computer-implemented method of claim 15, wherein the mobile monitoring application is further configured to output stored history data representing filtered parameter data monitored over a period of time (Swedlow; Paragraph 0026).

Regarding claim 17, the combination of Lisogurski and Swedlow teaches the computer-implemented method of claim 16, wherein outputting stored history data comprises presenting the stored history data to a user on a display of the mobile computing device (Swedlow; Paragraph 0025).

Regarding claim 18, the combination of Lisogurski and Swedlow teaches the computer-implemented method of claim 16, wherein outputting stored history data comprises exporting the stored history data to another computing device, i.e. display screen (Swedlow; Paragraph 0025).

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Claim 11 is rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Lisogurski (US 2011/0077473 A1) in view of Fouts (US Pat No. 5,692,505).

Regarding claim 11, Lisogurski teaches the computer-implemented method of claim 10, but does not explicitly teach wherein the signal processing comprises determining a noise signal, removing the noise signal, and outputting the filtered data. Fouts, however, teaches a method of data processing for oximeters, wherein the signal processing comprises determining a noise signal present in the raw data and filtering the raw data to remove the noise signal (Fouts; Col. 7 Lines 34-43); and outputting the filtered raw data as filtered parameter data (Fouts; Col. 7 Lines 58-65). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to combine the method of Lisogurski with the method of removing noise, as taught by Fouts, because noise signals are present in almost every raw physiological signals due to ambient light or motion artifact. Therefore, in order to improve accuracy of the physiological measurements, it would have been obvious to filter out the noise signal before outputting a measurement.

Claims 19-21 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Lisogurski (US 2011/0077473 A1) in view of Otto (US 2008/0211657 A1).

Regarding claim 19, Lisogurski teaches the computer-implemented method of claim 10, but does not explicitly teach connecting to a network using the mobile computing device and transmitting the filtered parameter data over the network. Otto, however, teaches a wireless sensor network system, further comprising connecting to a network using the mobile computing device, i.e. controller (Otto; 102 in Fig. 1) and transmitting the parameter data over the network (Otto; Paragraphs 0031 and 0037). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide the method of Lisogurski with a method

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of transmitting filtered physiological data over a network in order to allow wireless monitoring of patients in hospitals where clinicians need to monitor many different patients at the same time.

Regarding claim 20, the combination of Lisogurski and Otto teaches the computer-implemented method of claim 19, wherein the filtered parameter data is transmitted over the network to a calibration service, i.e. control logic in the controller (Otto; Paragraphs 0053 and 0066-0067), the method further comprising incorporating the filtered parameter data into a sensor data set (Otto; Paragraphs 0041-0042 and 0048). Although Otto does not explicitly teach incorporating filtered parameter data into a calibration data set, it would have been obvious to a person having ordinary skill in the art to incorporate filtered patient data into a calibration data set in order to configure the sensor specifically to the user that is using the sensor, especially since sensors can be used interchangeably by multiple patients at hospitals.

Regarding claim 21, the combination of Lisogurski and Otto teaches the computer-implemented method of claim 20, but does not explicitly teach further comprising using the calibration data set to generate a calibration curve. However, generating a calibration curve is a conventional method of graphically displaying the calibration data set. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to generate a calibration curve using the calibration data set of the combination of Lisogurski and Otto in order to make the calibration data set more easily-readable by the user or clinician as well as to easily monitor calibration trends.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to YOOJIN LEE whose telephone number is (571)270-7069. The examiner can normally be reached on MON-FRI: 8AM-5PM EST.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ROBERT (TSE) CHEN can be reached on 571-272-3672. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/YOOJIN LEE/
Examiner, Art Unit 3777

/TSE CHEN/
Supervisory Patent Examiner, Art Unit 3777

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AMENDMENTS TO THE SPECIFICATION

Please amend paragraph [0006] of the Specification as follows:

[0006] This disclosure describes embodiments of a mobile physiological sensor that can be conveniently used in conjunction with existing mobile devices of users in a variety of contexts. In certain embodiments, a physiological monitoring system can be designed to include a sensor and cable assembly with a processing board or card, and the system can be connectable to a mobile computing device, such as a smartphone, such that display of the monitored physiological data can occur on the computing device. The board or card can communicate the data for display with the mobile computing device wirelessly or through a physical and electrical connection with the cable assembly. In some embodiments, the board or card can include one or more signal processors and associated memory, I/O, and the like to provide monitored physiological data to applications executing on traditional smartphone processing environments, such that board or card handles advanced signal processing and the smartphone displays parameter data. In an embodiment, the board is housed in a portion of the cable such that it is not directly coupled to the sensor or the smartphone connector. This configuration has the advantage of mechanically isolating the board so that it does not encumber the sensor or the smart phone connection. As a result, the physiological monitoring system can be more portable than existing monitoring systems, thereby facilitating enhanced patient care for more patients.

Please amend paragraph [0006] of the Specification as follows:

[0008] Physiological monitoring systems such as those that are described herein enable oximeter use outside of the traditional hospital setting. This is beneficial for more comprehensive patient care. For instance, prior to a surgical procedure during which a patient will be sedated, such as by general anesthesia, a physician can be concerned about the patient's proclivity toward apnea. A portable oximetry sensor compatible with the patient's smartphone can be sent home with the patient prior to the procedure, and the sensor can be worn overnight. Data collected from the sensor can be passed to the smartphone and made available to the doctor, such as by uploading to the internet or being downloadable from the device, to identify a risk of hypoxemia. This example illustrates one of the many benefits of a portable oximetry system compatible with a common mobile computing device.

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REMARKS

In the present response, Applicant amends Claims 1-2 and 8-10. No new matter is added by these amendments, which are supported by at least the claims as originally filed and paragraphs [0053]-[0055] of the Specification as originally filed. Accordingly, Claims 1-21 are submitted for further consideration in light of the amendments illustrated in the foregoing section “Amendments to the Claims” and the following remarks.

Specification Objections

The Office Action objects to the Specification for the following informalities:

- In paragraph [0006], line 12, “board is house in a portion” should read “board is housed in a portion”
- In paragraph [0008], line 1, “such as are described herein” should read “such as those that are described herein”

Applicant thanks the Examiner for the helpful suggestions and has amended the Specification accordingly in the foregoing section “Amendments to the Specification.” As such, Applicant respectfully requests withdrawal of the objection to the Specification.

Claim Interpretation - 35 U.S.C. § 112 ¶ 6

Regarding the interpretation by the Office Action of Claims 1, 2, and 8 under 35 U.S.C. 112 ¶ 6, Applicant traverses the rejection, and for the reasons set forth below Applicant disagrees that Claims 1, 2, and 8 fall within the scope of 35 U.S.C. 112 ¶ 6, as means plus function claims.

Without necessarily agreeing with the rejection but to advance prosecution, as indicated above, Applicant has amended Claim 1 to recite “a physiological sensor configured to monitor one or more physiological parameters of a patient,” has amended Claim 2 to recite “wherein the port is connectable to the mobile computing device,” and has amended Claim 8 to remove the “module” recitation and to instead recite “a processor configured to execute instructions for...” the transmitting features.

Per MPEP § 2181, “a claim limitation that does not use the term “means” or “step” will trigger the rebuttable presumption that 35 U.S.C. 112(f) ... does not apply... This strong

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presumption may be overcome if the claim limitation is shown to use a non-structural term that is “a nonce word or a verbal construct that is not recognized as the name of structure” but is merely a substitute for the term “means” associated with functional language.” Following this, MPEP § 2181 provides a three-prong analysis for determining whether 35 U.S.C. 112(f) should apply, each prong of which must be met to apply 35 U.S.C. 112(f) to a claim limitation.

The first prong of the three-prong analysis requires that “the claim limitation uses the term “means” or “step” or a term used as a substitute for “means” that is a generic placeholder (also called a nonce term or a non-structural term having no specific structural meaning) for performing the claimed function.” Providing clarity regarding what may or may not constitute a generic placeholder, MPEP § 2181 explains that “35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, paragraph 6 will not apply if persons of ordinary skill in the art reading the specification understand the term to have a sufficiently definite meaning as the name for the structure that performs the function, even when the term covers a broad class of structures or identifies the structures by their function.” MPEP § 2181 further explains that “[f]or a term to be considered a substitute for “means,” and lack sufficient structure for performing the function, it must serve as a generic placeholder and thus not limit the scope of the claim to any specific manner or structure for performing the claimed function.”

Applicant submits that the terms “physiological sensor”, “port” and “processor” as recited in Claims 1, 2, and 8 are each structural terms with specific structural meanings understood to have sufficiently definite meaning by persons of ordinary skill in the art. Further, the terms “physiological sensor”, “port” and “processor” as recited in Claims 1, 2, and 8 each serve to limit the scope of the claim to a specific structure for performing the claimed function. Thus, Claims 1, 2, and 8 fail the first prong of the three-prong analysis.

The third prong of the three-prong analysis requires that “the term “means” or “step” or the generic placeholder is not modified by sufficient structure, material, or acts for performing the claimed function.” MPEP § 2181. Applicant respectfully submits that the terms “physiological sensor”, “port” and “processor” as recited in Claims 1, 2, and 8 recite sufficient structure to perform the recited functions without the need to resort to the specification for adequate understanding of the structure. Thus, Claims 1, 2, and 8 also fail the third prong of the three-prong analysis.

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Accordingly, Applicant submits that Claims 1, 2, and 8 fall outside of the scope of 35 U.S.C. 112 ¶ 6.

Art-Based Rejections— 35 USC §§ 102 and 103

The Office Action rejected Claims 1-2, 4, 6-7, 9-10, and 12-14 under 35 U.S.C. § 102(b) as allegedly anticipated by Lisogurski (US 2011/0077473).

The Office Action rejects Claim 3 under 35 U.S.C. § 103(a) as allegedly unpatentable over Lisogurski in view of Turricchia (US 2010/0198094).

The Office Action rejects Claim 5 under 35 U.S.C. § 103(a) as allegedly unpatentable over Lisogurski in view of Al-Ali (US 2011/0071370).

The Office Action rejects Claims 8 and 15-18 under 35 U.S.C. § 103(a) as allegedly unpatentable over Lisogurski in view of Swedlow (US 2006/0224059).

The Office Action rejects Claim 11 under 35 U.S.C. § 103(a) as allegedly unpatentable over Lisogurski in view of Fouts (US Pat. No. 5,692,505).

The Office Action rejects Claims 19-21 under 35 U.S.C. § 103(a) as allegedly unpatentable over Lisogurski in view of Otto (US 2008/0211657).

Applicant respectfully traverses each rejection and each assertion regarding what the reference discloses, and Applicant does not acquiesce in the validity of the rejections. To expedite allowance of this application, however, Applicant has amended independent Claims 1 and 10. As discussed below, Applicant submits that all of the pending claims are allowable over the cited references.

Independent Claim 1

The physiological monitoring system of amended Claim 1 in part includes:

“a cable including a processing board configured to establish an electrical signal connection between the physiological sensor and the mobile computing device, wherein the processing board receives raw data representing the monitored one or more physiological parameters and performs signal processing to provide filtered parameter data to the mobile computing device; and

an enclosure comprising:

a body portion surrounding the processing board,
a first bend relief on a first side of the body portion, and

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a second bend relief on a second side of the body portion, a first portion of the cable coupled between the physiological sensor and the processing board through the first bend relief and a second portion of the cable coupled between the processing board and the mobile computing device through the second bend relief.”

Lisogurski teaches a sensor-monitor interconnection system 10, as shown in Figure 1, reproduced below. *Lisogurski*, ¶ [0023]. A “short analog cable 18 may include a sensor connector 22 that joins to a sensor-side cable connector 24 of the sensor-monitor intercommunication cable 20,” and cable 20 “may include the sensor-side cable connector 24... and a monitor-side cable connector 28.” *Lisogurski*, ¶ [0023].

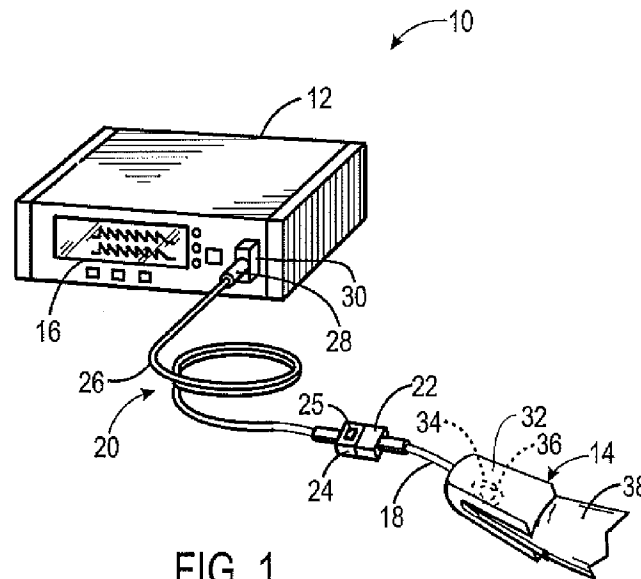


FIG. 1

Lisogurski, FIG 1

In a first embodiment of Lisogurski, “sensor-side cable connector 24 may receive analog data from the medical sensor 14, digitize the data, and transmit the digitized data to the monitor-side cable connector 28 via the digital cable 26.” *Lisogurski*, ¶ [0028]. The “monitor-side cable connector 28 may process the digitized data to obtain a physiological measurement, transmitting the determined physiological measurement to the patient monitor 12 via the monitor connector 30.” *Lisogurski*, ¶ [0030]. Accordingly, in the first embodiment of Lisogurski the processing aspects are split between the sensor-side cable connector 24 and the monitor-side cable connector 28. These components are coupled with a length of cable 20, and monitor-side cable connector 28 couples directly with the monitor connector 30.

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Thus, the first embodiment of Lisogurski does not teach at least “an enclosure comprising: a body portion surrounding the processing board, a first bend relief on a first side of the body portion, and a second bend relief on a second side of the body portion, a first portion of the cable coupled between the physiological sensor and the processing board through the first bend relief and a second portion of the cable coupled between the processing board and the mobile computing device through the second bend relief,” as recited by Claim 1.

In a second embodiment of Lisogurski, “the sensor-side cable connector 24 may transmit the received analog data to the monitor-side cable connector 28 without first digitizing the data,” and “the monitor-side cable connector 28 may instead digitize the analog data.” *Lisogurski*, ¶ [0029]. Again, in this embodiment the monitor-side cable connector 28 processes digitized data and transmits a determined physiological measurement to the patient monitor 12 via the monitor connector 30. *Lisogurski*, ¶ [0030]. Accordingly, in the second embodiment of Lisogurski the processing aspects are contained in the monitor-side cable connector 28, which couples directly with the monitor connector 30.

Thus, the second embodiment of Lisogurski also fails to teach at least “an enclosure comprising: a body portion surrounding the processing board, a first bend relief on a first side of the body portion, and a second bend relief on a second side of the body portion, a first portion of the cable coupled between the physiological sensor and the processing board through the first bend relief and a second portion of the cable coupled between the processing board and the mobile computing device through the second bend relief,” as recited by Claim 1.

For at least the foregoing reasons, Applicant respectfully submits that Lisogurski fails to teach each feature of Claim 1 as amended. Further, Applicant respectfully submits that the other art of record fails to remedy the defect of Lisogurski. Thus, Applicant requests that the rejection of Claim 1 under 35 U.S.C. § 102(b) be withdrawn.

Independent Claim 10

The method of amended Claim 10 in part includes:

“providing a portable physiological monitoring system comprising:
a physiological sensor configured to monitor one or more
physiological parameters of a patient,

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a cable including a processing board configured to establish an electrical signal connection between the sensor and a mobile computing device, and
an enclosure comprising:
a body portion surrounding the processing board,
a first bend relief on a first side of the body portion, and
a second bend relief on a second side of the body portion, a first portion of the cable coupled between the physiological sensor and the processing board through the first bend relief and a second portion of the cable coupled between the processing board and the mobile computing device through the second bend relief...”

For at least similar reasons to those discussed above with respect to Claim 1, the art of record fails to teach each feature of Claim 10 as amended. Thus, Applicant requests that the rejection of Claim 10 under 35 U.S.C. § 102(b) be withdrawn.

Discussion of Dependent Claims

Additionally, Applicant submits that the dependent claims also define over the cited references, not only because they depend from one of independent Claims 1 and 10, discussed above, but also on their own merit. Further, Applicant submits that the cited portions of Turricchia, Al-Ali, Swedlow, Fouts, and Otto fail to cure the defects of Lisogurski discussed above.

Thus, Applicant requests that all rejections under 35 U.S.C. § 102(b) and 35 U.S.C. § 103 be withdrawn.

Claim Rejections - 35 U.S.C. § 101

The Office Action rejects Claims 10-21 under 35 U.S.C. § 101 as allegedly directed to a judicial exception without significantly more. Applicant respectfully disagrees as set forth below.

The Supreme Court in *Alice Corporation Pty. Ltd. v. CLS Bank Intn'l, et al*, 573 U.S. ____ (2014) (“*Alice*”) set forth a two-part test for evaluating compliance with section 101. Part 1 considers whether the claim is directed to an abstract idea. Part 2, which is applied if the claim recites an abstract idea, considers whether the claim recites “significantly more” than the abstract idea. This two-part test is explained in the USPTO’s “Interim Guidance on Patent Subject Matter

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Eligibility” issued on December 16, 2014. For the reasons explained below, the claims comply with section 101 under the two-part test.

1. Claims 10-21 are not directed to an abstract idea.

Claims 10-21 are not directed to an abstract idea. Applicant respectfully disagrees with the Office Action’s characterization of the claims as being directed to an abstract idea for “providing a physiological monitoring system, generating a physiological signal, processing/filtering the signal, and transmitting filtered data to a mobile device, which are all considered an abstract idea.” Applicant respectfully submits that the claims are not directed to an abstract idea and should be considered subject-matter eligible.

This invention is fundamentally different from the financial business methods of *Alice* and *Bilski*. Specifically, claim 10 is directed to a particular use of **a cable-based processing board** to determine a specific condition of a patient. A “cable including a processing board” is a real-world hardware device. Respectfully, arguing that a claim having a cable-based processing board is abstract contravenes precedent and common sense.

Although the Supreme Court declined to define the term “abstract,” dictionaries provide a useful clue. Merriam-Webster defines “abstract” as “relating to or involving general ideas or qualities rather than specific people, objects, or actions.”¹ Dictionary.com defines “abstract” as “thought of apart from concrete realities, specific objects, or actual instances.”² The plain meaning of abstract describes the opposite of a device—such as a cable-based processing board—which is an object, as non-abstract as a claim element can possibly be.

This contrast is so stark that merely a glance at *Alice* quickly confirms that the Supreme Court was not interested in the Patent Office rejecting claims to the use of cable-based processing boards in a specific and defined way. Indeed, the first instance of “abstract” in *Alice* calls it what it is—an “abstract **idea**.” *Alice Corp. PTY. Ltd. v. CLS Bank Int’l*, 573 U.S. ____ (2014) (slip op. at 1) (emphasis added). The Court was not concerned with stripping patent-eligibility for *specific uses of cable-based processing boards*, which are *objects*, but was concerned with inventors patenting certain types of *ideas* merely implemented in a generic computer. A cable-based processing board is fundamentally not an idea. The present claims are nothing like the claims in

¹ <http://www.merriam-webster.com/dictionary/abstract> (emphasis added).

² <http://dictionary.reference.com/browse/abstract?s=t> (emphasis added).

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Alice that have set off a flurry of Section 101 rejections. These claims are directed to health-preserving medical device technology that goes to the very heart of what the Founding Fathers created patents for—“to promote the Progress of Science and useful Arts.” See U.S. Constitution, Art. I, § 8.

The Supreme Court in *Alice* cautioned that the “abstract idea” concept must be wielded judiciously “lest it swallow all of patent law.” *Alice*, slip op. at 6 (citing *Mayo Collaborative Services v. Prometheus Labs. Inc.*, 566 U.S. at ___ (slip op. at 2)). This case attests to the very dangers of extending the abstract idea analysis far beyond the bounds of *Alice*. If specific uses of cable-based processing boards are now considered to be abstract, then the Office can arbitrarily label *any claimed method* as abstract because the same analysis would apply in every instance. Such a result cannot be correct.

Representative claim 1 also includes specific processing features that process the obtained physiological signal to output a useful and concrete result. The one or more physiological parameters determined by this claim are transmitted to the mobile device. As explained by the Specification at paragraph [0052], “the mobile device 220 can not have sufficient processing power to handle the conversion of raw data 204 to identifiable parameters 226.” “Complex operations such as noise filtering and signal processing can require specialized processing or significant computational overhead, such that a typical user mobile device can not have sufficient processing power. Accordingly, the processing module 130 can perform signal processing on raw data received from the sensor and can provide physiological parameters as an output to a display and/or storage device.” *Specification*, ¶ [0047]. As a result, a patient can remotely monitor a variety of physiological parameters from anywhere using their cell phone or other mobile device, because the cable-based processing board performs the signal processing that the device cannot. Patients will live, get well, and be monitored more effectively—even to the point where lives can be saved—by the claimed features. These features recite the epitome of non-abstractness.

The Office Action takes the position that the claims are directed to a fundamental data processing practice in the art. However, as set forth above, the cited references do not teach all of the limitations of the pending claims. Moreover, simply reciting a mathematical formula or manipulating data in a claim does not render the claim unpatentable, and the Office cannot simply ignore the rest of the limitations in the claims.

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Accordingly, Claims 10-21 are not directed to an abstract idea and the claims satisfy all requirements for patent eligibility under 35 U.S.C. § 101. Thus, Applicant respectfully requests withdrawal of the rejection of Claims 10-21 under 35 U.S.C. § 101 and allowance of the claims.

2. Further Analysis under the PTO Guidelines

Additionally, Applicant respectfully submits that Claims 10-21 are patent eligible under either the “streamlined” eligibility analysis or the “full” eligibility analysis set forth in the 2014 Interim Guidance on Patent Subject Matter Eligibility, 79 Fed. Reg. 74,618–74,61 (Dec. 16, 2014) (hereinafter “Revised Interim Guidance”).

a. Claims 10-21 Are Patent Eligible Under the Streamlined Eligibility Analysis

Applicant submits that the “streamlined” eligibility analysis is appropriate for the claims at issue, and that under the streamlined analysis, Claims 10-21 are patent eligible.

The Revised Interim Guidance states:

For purposes of efficiency in examination, a streamlined eligibility analysis can be used for a claim that may or may not recite a judicial exception but, when viewed as a whole, *clearly does not seek to tie up any judicial exception* such that others cannot practice it. Such claims do not need to proceed through the full analysis herein as their eligibility will be self-evident.

Revised Interim Guidance, 79 Fed. Reg. at 74,625 (emphasis added).

Applicant respectfully submits that Claims 10-21 also clearly do not seek to tie up any possible judicial exceptions, and therefore do not require analysis under the two-part *Alice* test. The Office Action alleges that claims are directed to a well-understood, routine, and conventional practices coupled with the recitations of “insignificant post-solution activity and/or data gathering... routine and conventional data processing steps... and/or conventional elements of a computing environment.” *Office Action*, page 4. Applicant respectfully disagrees. Claims 10-21 set forth specific practices and interactions (as detailed within the respective claims) for determining a physiological measurement that do not tie up conventional practices of collecting and processing data.

For example, representative claim 10 recites specific limitations that are not well-understood, conventional, or routine, including:

providing a portable physiological monitoring system comprising:
a physiological sensor configured to monitor one or more physiological parameters of a patient,

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a cable including a processing board configured to establish an electrical signal connection between the sensor and a mobile computing device, and an enclosure comprising:
a body portion surrounding the processing board,
a first bend relief on a first side of the body portion, and
a second bend relief on a second side of the body portion, a first portion of the cable coupled between the physiological sensor and the processing board through the first bend relief and a second portion of the cable coupled between the processing board and the mobile computing device through the second bend relief...

The processing board in such an enclosure can provide one or more physiological measurements to a “mobile device 220 [that] can not have sufficient processing power to handle the conversion of raw data 204 to identifiable parameters 226.” *Specification*, ¶ [0052]. Additionally, claim 10 does not recite a generic computer structure that performs generic computer functions. Rather, claim 10 recites using a specifically configured cable-based processor board to determine one or more physiological parameters, the parameters derived from signals received from “a physiological sensor configured to monitor one or more physiological parameters of a patient.” Such a sensor is a specialized hardware device that performs highly specialized functions in order to determine oxygen saturation measurements. Considering the cable-based processor as a generic computer structure would improperly mischaracterize and ignore the specific recitations of the claims.

Thus, it is clear that Claims 10-21 do not seek to tie up or preempt any abstract ideas merely directed to routine and conventional data processing or conventional elements of a computing environment. Rather, the claims recite specific limitations associated with determining one or more physiological parameters in accordance with the specific practices and hardware of a mobile patient monitoring environment.

Because one of skill in the art could not reasonably conclude that amended Claims 10-21 tie up or otherwise preempt any abstract ideas related to routine and conventional data processing or conventional elements of a computing environment, Applicant submits that a full analysis of Claims 10-21 under the two-part *Alice* test is not required. Accordingly, Applicant submits that Claims 10-21 comply with 35 U.S.C. § 101, that the rejections under 35 U.S.C. § 101 should be withdrawn, and that the claims are now in condition for allowance.

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b. Claims 10-21 Are Patent Eligible Under the Full Eligibility Analysis

Notwithstanding, in the instance that the Office decides to conduct a full eligibility analysis of the claims as described in the Revised Interim Guidance, Applicant respectfully submits that Claims 10-21 are patent eligible.

Stating reliance on Supreme Court precedent, the Revised Interim Guidance provides guidelines for the full eligibility analysis as follows:

Determine whether the claim is directed to a law of nature, a natural phenomenon, or an abstract idea (judicial exceptions) . . . [and d]etermine whether any element, or combination of elements, in the claim is sufficient to ensure that the claim amounts to significantly more than the judicial exception.

Revised Interim Guidance, Fed. Reg. at 74,618, 74,624.

For at least the following reasons, Applicant respectfully submits that Claims 10-21 are patent eligible under the full eligibility analysis.

i. Claims 10-21 Are Not Directed to an Abstract Idea

As discussed above, Claims 10-21 are not directed to an abstract idea. The Revised Interim Guidance, establishes that a “claim is directed to a judicial exception when a law of nature, a natural phenomenon, or an abstract idea is recited (*i.e.*, set forth or described) in the claim.” *Id.* at 74,622, cols. 1–2 (stating that “mathematical formulas are considered to be [a judicial] exception”). The Revised Interim Guidance further makes clear that, in order for a claim to be considered as “directed to” a judicial exception, the claim must pose a risk of tying up the excepted subject matter and preempting others from using the abstract idea. *See id.* at 74,622, col. 1.

There is no risk that Claims 10-21 could “t[ie] up the excepted subject matter and preempt[] others from using the abstract idea,” because one of skill in the art would readily appreciate Claims 10-21 are not directed to an abstract idea and do not seek to tie up or preempt the conventional practice of data processing or of conventional computing elements. On the contrary, Claims 10-21 are associated with specific features for determining one or more physiological parameters in accordance with the specific practices and hardware recited in the claims. Thus, Claims 10-21 satisfy Part 1 of the two-part Alice test.

Further, Applicant respectfully submits that the allegation at page 4 of the Office Action that Claims 10-21 are directed to “insignificant post-solution activity and/or data gathering... routine and conventional data processing steps... and/or conventional elements of a computing

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environment” oversimplifies the claims in a manner that the U.S. Supreme Court (and the Revised Interim Guidance) has cautioned against. In particular, Applicant notes that the U.S. Supreme Court has stated that “[a]t some level, ‘all inventions . . . embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas.’” *Alice Corp. v. CLS Bank Int’l*, 573 U.S. ____ at 6, 134 S.Ct. 2347, 2354 (2014).

The characterizations of the Office Action of the recited elements are an oversimplification of the claims and ignore many of the claimed elements. For example, in order to characterize Claim 10 as merely directed to collecting and processing data, at least the following underlined recitations of amended Claim 10 are ignored:

A computer-implemented method of mobile physiological monitoring, the method comprising:
 providing a portable physiological monitoring system comprising:
 a physiological sensor configured to monitor one or more physiological parameters of a patient,
 a cable including a processing board configured to establish an electrical signal connection between the sensor and a mobile computing device, and
 an enclosure comprising:
 a body portion surrounding the processing board,
 a first bend relief on a first side of the body portion, and
 a second bend relief on a second side of the body portion, a first portion of the cable coupled between the physiological sensor and the processing board through the first bend relief and a second portion of the cable coupled between the processing board and the mobile computing device through the second bend relief;
 generating raw data representing the monitored one or more physiological parameters using the physiological sensor;
 receiving the raw data at the processing board via the first portion of the cable;
 performing signal processing on the raw data using the processing board, wherein the signal processing generates filtered parameter data; and
 transmitting the filtered parameter data via the second portion of the cable to the mobile computing device.

Applicant submits that the foregoing meaningful recitations clearly show that the claims as amended are not directed to an abstract idea. For example, “providing a portable physiological monitoring system comprising: a cable including a processing board configured to establish an electrical signal connection between the sensor and a mobile computing device, and an enclosure comprising: a body portion surrounding the processing board, a first bend relief on a first side of the body portion, and a second bend relief on a second side of the body portion, a first portion of

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the cable coupled between the physiological sensor and the processing board through the first bend relief and a second portion of the cable coupled between the processing board and the mobile computing device through the second bend relief” or performing the processing steps “via the processing board” cannot be reduced to generically collecting data.

Thus, one skilled in the art could not reasonably dismiss the foregoing meaningful features as merely an abstract idea and, on the contrary, would conclude that these features do not preempt all implementations of receiving, processing, and outputting measurements. Thus, Applicant submits that the abstraction provided by the Office is overreaching and an oversimplification of the recitations of representative independent Claim 10, and that the recitations of Claim 10 as amended is not directed to merely well-understood, routine, and conventional practices.

For at least the above reasons, Applicant submits that Claims 10-21 are not directed to merely fundamental economic practices and therefore satisfy Part 1 of the two-part Alice test.

ii. Claims 10-21 Are Directed to a Patent-Eligible Concept

The U.S. Supreme Court has stated that “an invention is not rendered ineligible for patent simply because it involves an abstract concept” and that “‘application’ of such concepts ‘to a new and useful end,’ we have said, remains eligible for patent protection.” *Alice*, 134 S.Ct. at 2354. Thus, even in the event that the Office argues that the features recited in Claims 10-21 are directed to an abstract idea, to which Applicant strongly disagrees, Applicant respectfully submits that, after considering the claim recitations as amended, individually and in combination, the claim recitations transform the nature of the claims into a patent-eligible concept.

The Revised Interim Guidance further indicates that when a claim includes an abstract idea and meaningful limitations beyond generally linking the use of an abstract idea to a particular technological environment, it may qualify as “significantly more than the abstract idea” and therefore be patent eligible. *See* Revised Interim Guidance, Fed. Reg. at 74,624 (citing *Alice*, 134 S.Ct. at 2360 and *Diamond v. Diehr*, 450 U.S. at 177–178). Applicant submits that to reject Claims 10-21 under 35 U.S.C. § 101 would ignore meaningful claim elements amounting to “significantly more than the abstract idea” as prohibited by the Revised Interim Guidance.

As discussed above, Claim 10 recites specific elements that constitute significantly more than merely receiving, processing, and outputting measurements. *See, e.g.*, Revised Interim

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Guidance, Fed. Reg. at 74,624, col. 2 (“Adding a specific limitation other than what is well-understood, routine and conventional in the field” may be enough “to qualify as ‘significantly more’ when recited in a claim.”). In conducting the instructed analysis, Applicant submits that meaningful claim recitations (such as those noted above) have been ignored in the Office Action. The recitations of the claims as amended do not merely link an abstract idea to a particular technological environment, but rather set forth specific interactions for determining an oxygen saturation measurement in body tissue in accordance with the specific practices and hardware.

Moreover, the Revised Interim Guidance indicates that whether a claim recites “significantly more” than an abstract idea is a question of whether the claim “is more than a drafting effort designed to monopolize the exception.” Revised Interim Guidance, Fed. Reg. at 74,624, col. 1. Applicant submits that the recitations of Claim 10 as amended are more specific and focused in scope than the abstract idea alleged in the Office Action, and that the allowance of Claim 10 would not grant a monopoly on collecting and processing data. *See DDR Holdings, LLC v. Hotels.com, L.P.*, No. 2013-1505, slip op. at 23 (Fed. Cir. Dec. 5, 2014) (holding that the claims do not preempt the abstract idea but rather recite a “specific way” of creating a composite web page, and thus the claims include “‘additional features’ that ensure the claims are ‘more than a drafting effort designed to monopolize the [abstract idea]’”).

Even if, *arguendo*, the claims involve an abstract idea at some level, they are directed to “significantly more” than an abstract idea, and thus comply with section 101 under Part 2 of the two-part test. Indeed, as stated in *Alice*, “... an invention is not rendered ineligible for patent simply because it involves an abstract concept. Application of such concepts to a new and useful end remain eligible for patent protection.” *Alice*, slip op. at p. 4, citing *Diamond v. Diehr*. Thus, the claims at issue cannot properly be rejected under section 101 merely because they may, at some level, involve an abstract concept.

Indeed, independent Claim 10 recites far more than the alleged abstract idea of providing a sensor and processing data. For example, as discussed above, the claim states that the method comprises (emphasis added):

...generating raw data representing the monitored one or more physiological parameters using the physiological sensor;
receiving the raw data at the processing board via the first portion of the cable;
performing signal processing on the raw data using the processing board, wherein the signal processing generates filtered parameter data; and

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transmitting the filtered parameter data via the second portion of the cable to the mobile computing device.

As discussed above, the structure of the cable-based processing board enclosure distinguishes the claimed technology from the cited art. Thus, the claims recite significantly more than the alleged abstract idea. Additional features that represent significantly more than the alleged abstract idea are recited throughout the dependent claims.

Thus, Claims 10-21 are directed to “significantly more” than an abstract idea, and comply with part two of the two-part Alice test.

In summary, Applicant submits that Claims 10-21 are not directed to an abstract idea, do not seek to preempt or tie up any judicial exception, and need not be analyzed under the two-part *Alice* test. Further, even if such analysis were conducted, Applicant submits Claims 10-21 satisfy all requirements for patent eligibility under 35 U.S.C § 101. Thus, Applicant respectfully requests withdraw of the rejection of Claims 10-21 under 35 U.S.C. § 101 and allowance of the claims.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicant is not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

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Conclusion

The Applicant has endeavored to address all of the Examiner's concerns as expressed in the outstanding Office Action. In view of the foregoing amendments and remarks, Applicant respectfully requests reconsideration and withdrawal of the outstanding rejections, and that the claims now be found in condition for allowance.

Any claim amendments which are not specifically discussed in the above remarks are not made for patentability purposes, and it is believed that the claims would satisfy the statutory requirements for patentability without the entry of such amendments. Rather, these amendments have only been made to increase claim readability, to improve grammar, and to reduce the time and effort required of those in the art to clearly understand the scope of the claim language.

Should the Examiner have any remaining concerns that might prevent the prompt allowance of the application, the Examiner is respectfully invited to contact the undersigned at the telephone number below.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: February 12, 2016

By: /Lauren Hockett/

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AMENDMENTS TO THE CLAIMS

1. **(Currently Amended)** A physiological monitoring system comprising:
a physiological sensor configured to monitor one or more physiological parameters of a patient;
a mobile computing device comprising a display; [[and]]
a cable including a processing board configured to establish an electrical signal connection between the physiological sensor and the mobile computing device, wherein the processing board receives data representing the monitored one or more physiological parameters and performs signal processing to provide filtered parameter data to the mobile computing device; and
an enclosure comprising:
a body portion surrounding the processing board,
a first bend relief on a first side of the body portion, and
a second bend relief on a second side of the body portion, a first portion of the cable coupled between the physiological sensor and the processing board through the first bend relief and a second portion of the cable coupled between the processing board and the mobile computing device through the second bend relief.
2. **(Currently Amended)** The physiological monitoring system of claim 1, ~~wherein the sensor is coupled to the processing board using a first portion of the cable, and wherein the processing board is coupled to a port using a second portion of the cable, wherein the port configured to be~~ is connectable to the mobile computing device.
3. **(Original)** The physiological monitoring system of claim 1, wherein the processing board comprises a digital processing board and an analog processing board.
4. **(Original)** The physiological monitoring system of claim 1, wherein the processing board is in communication with an information element.
5. **(Original)** The physiological monitoring system of claim 1, wherein the mobile computing device provides a power signal to the processing board and the physiological sensor.
6. **(Original)** The physiological monitoring system of claim 1, wherein the mobile computing device presents the filtered parameter data to a user on the display.

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7. (Original) The physiological monitoring system of claim 1, wherein the mobile computing device further comprises storage configured to store the filtered parameter data.

8. **(Currently Amended)** The physiological monitoring system of claim 1, wherein the mobile computing device further comprises a ~~network communication module processor~~ configured to ~~transmit~~ execute instructions for transmitting, via a network connection, the filtered parameter data to at least one of a calibration service, a physician computing device, or a medical facility patient database.

9. **(Currently Amended)** The physiological monitoring system of claim 1, wherein the physiological sensor comprises one or more of a pulse oximeter, capnometer, capnograph, acoustic respiratory sensor, electroencephalograph, electrocardiograph, or temperature sensor.

10. **(Currently Amended)** A computer-implemented method of mobile physiological monitoring, the method comprising:

providing a portable physiological monitoring system comprising:

a physiological sensor configured to monitor one or more physiological parameters of a patient, [[and]]

a cable including a processing board configured to establish an electrical signal connection between the sensor and a mobile computing device, and

an enclosure comprising:

a body portion surrounding the processing board,

a first bend relief on a first side of the body portion, and

a second bend relief on a second side of the body portion, a first portion of the cable coupled between the physiological sensor and the processing board through the first bend relief and a second portion of the cable coupled between the processing board and the mobile computing device through the second bend relief;

generating raw data representing the monitored one or more physiological parameters using the physiological sensor;

receiving the raw data at the processing board via the first portion of the cable;

performing signal processing on the raw data using the processing board, wherein the signal processing generates filtered parameter data; and

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transmitting the filtered parameter data via the second portion of the cable to the mobile computing device.

11. (Original) The computer-implemented method of claim 10, wherein the signal processing comprises:

determining a noise signal present in the raw data;
filtering the raw data to remove the noise signal; and
outputting the filtered raw data as filtered parameter data.

12. (Original) The computer-implemented method of claim 10, wherein the filtered parameter data comprises one or more of oxygen saturation, pulse rate, perfusion index, signal quality, oxygen content, carboxyhemoglobin, methemoglobin, and acoustic respiration rate.

13. (Original) The computer-implemented method of claim 10, wherein transmitting the filtered parameter data to the mobile computing device comprises transmitting the filtered parameter data through the cable and a connection port to the mobile computing device.

14. (Original) The computer-implemented method of claim 10, wherein transmitting the filtered parameter data to the mobile computing device comprises transmitting the filtered parameter data through the cable to a wireless communication module, wherein the filtered parameter data is transmitted wirelessly to the mobile computing device from the wireless communication module.

15. (Original) The computer-implemented method of claim 10, further comprising providing a mobile monitoring application configured to track and display the filtered parameter data.

16. (Original) The computer-implemented method of claim 15, wherein the mobile monitoring application is further configured to output stored history data representing filtered parameter data monitored over a period of time.

17. (Original) The computer-implemented method of claim 16, wherein outputting stored history data comprises presenting the stored history data to a user on a display of the mobile computing device.

18. (Original) The computer-implemented method of claim 16, wherein outputting stored history data comprises exporting the stored history data to another computing device.

19. (Original) The computer-implemented method of claim 10, further comprising:

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connecting to a network using the mobile computing device; and
transmitting the filtered parameter data over the network.

20. (Original) The computer-implemented method of claim 19, wherein the filtered parameter data is transmitted over the network to a calibration service, the method further comprising incorporating the filtered parameter data into a calibration data set

21. (Original) The computer-implemented method of claim 20, further comprising using the calibration data set to generate a calibration curve.

MASIMO.925A

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor	:	Bilal Muhsin
App. No.	:	14/033315
Filed	:	September 20, 2013
For	:	PHYSIOLOGICAL MONITOR WITH MOBILE COMPUTING DEVICE CONNECTIVITY
Examiner	:	Lee, Yoojin
Art Unit	:	3777
Conf. No.	:	9323

RESPONSE TO NON-FINAL OFFICE ACTION

Mail Stop Amendment

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In response to the non-final Office Action of August 13, 2015, Applicant submits the following amendments and remarks in the above-identified application.

Amendments to the Specification begin on page 2 of this paper.

Amendments to the Claims are reflected in the listing of claims which begins on page 3 of this paper.

Remarks/Arguments begin on page 7 of this paper.



UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/033,315	09/20/2013	Bilal Muhsin	MASIMO.925A	9323
64735 7590 03/29/2016 KNOBBE, MARTENS, OLSON & BEAR, LLP 2040 MAIN STREET FOURTEENTH FLOOR IRVINE, CA 92614			EXAMINER LEE, YOOJIN	
			ART UNIT 3777	PAPER NUMBER
			NOTIFICATION DATE 03/29/2016	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jayna.cartee@knobbe.com
efiling@knobbe.com

Office Action Summary	Application No. 14/033,315	Applicant(s) MUHSIN ET AL.	
	Examiner YOOJIN LEE	Art Unit 3777	AIA (First Inventor to File) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on 02/12/2016.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☒ Claim(s) 1-21 is/are pending in the application.
5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☒ Claim(s) 1-21 is/are rejected.

8) ☐ Claim(s) _____ is/are objected to.

9) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

10) ☐ The specification is objected to by the Examiner.

11) ☒ The drawing(s) filed on 09/20/2013 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a) ☐ All b) ☐ Some** c) ☐ None of the:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)
Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.

4) ☐ Other: _____.

Application/Control Number: 14/033,315

Page 2

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DETAILED ACTION

Notice of Pre-AIA or AIA Status

1. The present application is being examined under the pre-AIA first to invent provisions.

Claim Interpretations - 35 USC § 112

The following is a quotation of 35 U.S.C. 112(f):

(f) Element in Claim for a Combination. – An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

The following is a quotation of pre-AIA 35 U.S.C. 112, sixth paragraph:

An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

2. Claim limitations and “processor configured to execute instructions...” has/have been interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, because it uses/they use a generic placeholder “processor” coupled with functional language “configured to execute instructions” without reciting sufficient structure to achieve the function. Furthermore, the generic placeholder is not preceded by a structural modifier.

Since the claim limitation(s) invokes 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, claim(s) 8 has/have been interpreted to cover the corresponding structure described in the specification that achieves the claimed function, and equivalents thereof.

If applicant wishes to provide further explanation or dispute the examiner’s interpretation of the corresponding structure, applicant must identify the corresponding structure with reference to the specification by page and line number, and to the drawing, if any, by reference characters in response to this Office action.

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If applicant does not intend to have the claim limitation(s) treated under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, applicant may amend the claim(s) so that it/they will clearly not invoke 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, or present a sufficient showing that the claim recites/recite sufficient structure, material, or acts for performing the claimed function to preclude application of 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph.

For more information, see MPEP § 2173 *et seq.* and *Supplementary Examination Guidelines for Determining Compliance With 35 U.S.C. 112 and for Treatment of Related Issues in Patent Applications*, 76 FR 7162, 7167 (Feb. 9, 2011).

Claim Rejections - 35 USC § 103

3. The following is a quotation of pre-AIA 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-2, 4, 6-7, 9-10, and 12-14 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Lisogurski (US 2011/0077473 A1) in view of Al-Ali (US 2008/0071153 A1).

Regarding claim 1, Lisogurski teaches a physiological monitoring system comprising a physiological sensor configured to monitor one or more physiological parameters of a patient (Lisogurski; 14 in Fig. 1); a mobile computing device (Lisogurski; 12 in Fig. 1) comprising a display (Lisogurski; 16 in Fig. 1); and a cable including a processing board (Lisogurski; 20 in Fig. 1 and Paragraph 0040) configured to establish an electrical signal connection between the

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physiological sensor and the mobile computing device, wherein the processing board receives raw data representing the monitored one or more physiological parameters and performs signal processing to provide filtered parameter data to the mobile computing device (Lisogurski; Paragraph 0047); and an enclosure comprising a body portion (Lisogurski; 24 in Fig. 1) surrounding the processing board, i.e. “the microprocessor 56 is incorporated into the sensor-side cable connector 24” (Lisogurski; Paragraph 0040), a first portion of the cable (Lisogurski; 22 in Fig. 1) coupled between the physiological sensor (Lisogurski; 14 in Fig. 1) and the processing board (Lisogurski; Paragraph 0040 – processing board is incorporated in the connector) and a second portion of the cable (Lisogurski; 24 in Fig. 1) coupled between the processing board (Lisogurski; Paragraph 0040 – processing board is incorporated in the connector) and the mobile computing device (Lisogurski; 12 in Fig. 1). Although Lisogurski teaches structures that resemble a first bend relief on a first side of the body portion (Lisogurski; 22 in Fig. 1) and a second bend relief on a second side of the body portion (Lisogurski; 24 in Fig. 1), Lisogurski does not explicitly teach a first and second bend relief. Al-Ali, however, teaches a bend relief (Al-Ali; 1500 in Fig. 8C) on a first side of the body portion (Al-Ali; 1200 in Fig. 8C). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide the system of Lisogurski with a first bend relief on a first side of the body portion and a second bend relief on a second side of the body portion in order to protect the cable and cable wires proximate the body (Al-Ali; Paragraph 0039).

Regarding claim 2, the combination of Lisogurski and Al-Ali teaches the physiological monitoring system of claim 1, wherein the processing board is coupled to a port (Lisogurski; 30 in Fig. 1) using a second portion of the cable (Lisogurski; 26 and 28 in Fig. 1), wherein the port is connectable to the mobile computing device (Lisogurski; 12 in Fig. 1).

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Regarding claim 4, the combination of Lisogurski and Al-Ali teaches the physiological monitoring system of claim 1, wherein the processing board (Lisogurski; 56 in Fig.3) is in communication with an information element (Lisogurski; 48 in Fig. 3 and Paragraphs 0036 and 0038).

Regarding claim 6, the combination of Lisogurski and Al-Ali teaches the physiological monitoring system of claim 1, wherein the mobile computing device presents the filtered data to a user on the display (Lisogurski; Paragraph 0047).

Regarding claim 7, the combination of Lisogurski and Al-Ali teaches the physiological monitoring system of claim 1, wherein the mobile computing device further comprises storage configured to store the filtered parameter data (Lisogurski; Paragraph 0038).

Regarding claim 9, the combination of Lisogurski and Al-Ali teaches the physiological monitoring system of claim 1, wherein the physiological sensor comprises one or more of a pulse oximeter, capnometer, capnograph, acoustic respiratory sensor, electroencephalograph, electrocardiograph, or temperature sensor (Lisogurski; Paragraph 0021).

Regarding claim 10, the combination of Lisogurski and Al-Ali teaches a computer-implemented method of mobile physiological monitoring, the method comprising providing a portable physiological monitoring system comprising a physiological sensor configured to monitor one or more physiological parameters of a patient (Lisogurski; 14 in Fig. 1), and a cable including a processing board (Lisogurski; 20 in Fig. 1 and Paragraph 0040) configured to establish an electrical connection between the sensor and a mobile computing device (Lisogurski; Paragraph 0040), and an enclosure comprising a body portion surrounding the processing board (Lisogurski; 24 in Fig. 1 and Paragraph 0040), a first bend relief (Al-Ali; 1500 in Fig. 8C) on a first side of the body portion (Lisogurski; 22 in Fig. 1 – see rejection for claim 1), and a second bend relief (Al-Ali; 1500 in Fig. 8C) on a second side of the body portion

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(Lisogurski; 24 in Fig. 1 - see rejection for claim 1), a first portion of the cable (Lisogurski; 22 in Fig. 1) coupled between the physiological sensor (Lisogurski; 14 in Fig. 1) and the processing board (Lisogurski; Paragraph 0040) through the first bend relief (Al-Ali; 1500 in Fig. 8C) and a second portion of the cable (Lisogurski; 24 in Fig. 1) coupled between the processing board (Lisogurski; Paragraph 0040) and the mobile computing device (Lisogurski; 12 in Fig. 1) through the second bend relief (Al-Ali; 1500 in Fig. 8C); generating raw data representing the monitored one or more physiological parameters using the sensor (Lisogurski; Paragraph 0046); receiving the raw data at the processing board (Lisogurski; Paragraph 0047); performing signal processing on the raw data using the processing board, wherein the signal processing generates filtered parameter data (Lisogurski; Paragraph 0047); and transmitting the filtered parameter data to the mobile computing device (Lisogurski; Paragraph 0047).

Regarding claim 12, the combination of Lisogurski and Al-Ali teaches the computer-implemented method of claim 10, wherein the filtered parameter data comprises pulse rate or oxygen saturation (Lisogurski; Paragraph 0047).

Regarding claim 13, the combination of Lisogurski and Al-Ali teaches the computer-implemented method of claim 10, wherein transmitting the filtered parameter data to the mobile computing device comprises transmitting the filtered parameter data through the cable (Lisogurski; 20 in Fig. 1) and a connection port (Lisogurski; 30 in Fig. 1) to the mobile computing device (Lisogurski; Paragraph 0047 and Fig. 6).

Regarding claim 14, the combination of Lisogurski and Al-Ali teaches the computer-implemented method of claim 10, wherein transmitting the filtered parameter data to the mobile computing device comprises transmitting the filtered parameter data through the cable to a wireless communication module (Lisogurski; 120 in Fig. 10), wherein the filtered parameter data

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is transmitted wirelessly to the mobile computing device from the wireless communication module (Lisogurski; Paragraph 0055 and Fig. 10).

5. Claim 3 is rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Lisogurski (US 2011/0077473 A1) in view of Al-Ali (US 2008/0071153 A1), and further in view of Turicchia (US 2010/0198094 A1).

Regarding claim 3, the combination of Lisogurski and Al-Ali teaches the physiological monitoring system of claim 1, but does not explicitly teach wherein the processing board comprises both a digital processing board and an analog processing board. However, Turicchia teaches a wearable monitoring system, wherein the processing board comprises both a digital processing board and an analog processing board (Turicchia; Paragraph 0043). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide the system of the combination of Lisogurski and Al-Ali with an analog processor and a digital processor in order to receive and process physiological signals from monitoring sensors, and to trigger a visual or audible alarm in the event that a patient requires medical attention.

6. Claim 5 is rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Lisogurski (US 2011/0077473 A1) in view of Al-Ali (US 2008/0071153 A1), and further in view of Al-Ali '370 (US 2011/0071370 A1).

Regarding claim 5, the combination of Lisogurski and Al-Ali teaches the physiological monitoring system of claim 1, but does not explicitly teach wherein the mobile computing device provides a power signal to the processing board and the sensor. Al-Ali '370, however, teaches a sensor module (Al-Ali '370; Fig. 6) wherein an external device provides a power signal to the processing board and the sensor (Al-Ali '370; Paragraph 0026). Although Al-Ali '370 does not

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explicitly teach a mobile computing device providing a power signal to the processing board and the sensor, it is conventional to connect a sensor via cable to a mobile computing device, i.e. monitor, in order to provide power to the sensor during operation. Also, incorporating portable batteries to a physiological sensor could be disadvantageous because the battery-life becomes significantly shorter and the sensor could stop taking measurements after a certain period of time. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide the system of the combination of Lisogurski and Al-Ali with a mobile computing device that provides a power signal to the processing board and the sensor in order to increase battery-life and to make sure the patient is continuously monitored even over a period of days.

7. Claims 8 and 15-18 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Lisogurski (US 2011/0077473 A1) in view of Al-Ali (US 2008/0071153 A1), and further in view of Swedlow (US 2006/0224059 A1).

Regarding claim 8, the combination of Lisogurski and Al-Ali teaches the physiological monitoring system of claim 1, but does not explicitly teach a network communication module configured to transmit the filtered parameter data to at least one of a calibration service, a physician computing device, or a medical facility patient database. Swedlow, however, teaches an oximeter system comprising a processor configured to execute instructions for transmitting, via a network connection, the filtered parameter data to a medical facility patient database (Swedlow; Paragraphs 0028-0029). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide the system of the combination of Lisogurski and Al-Ali with a network communication module, as taught by Swedlow, in order to

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easily transmit stored patient information whenever a patient needs to be transferred to a different room in a hospital or a different medical facility.

Regarding claim 15, the combination of Lisogurski, Al-Ali, and Swedlow teaches the computer-implemented method of claim 10, further comprising providing a mobile monitoring application, i.e. memory chip, configured to track and display the filtered parameter data (Swedlow; Paragraph 0025). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide the method of the combination of Lisogurski and Al-Ali with a mobile monitoring application, as taught by Swedlow, in order to monitor a trend in a patient's physiological condition in order to observe any health improvements or deterioration for diagnostic or therapeutic purposes.

Regarding claim 16, the combination of Lisogurski, Al-Ali, and Swedlow teaches the computer-implemented method of claim 15, wherein the mobile monitoring application is further configured to output stored history data representing filtered parameter data monitored over a period of time (Swedlow; Paragraph 0026).

Regarding claim 17, the combination of Lisogurski, Al-Ali, and Swedlow teaches the computer-implemented method of claim 16, wherein outputting stored history data comprises presenting the stored history data to a user on a display of the mobile computing device (Swedlow; Paragraph 0025).

Regarding claim 18, the combination of Lisogurski, Al-Ali, and Swedlow teaches the computer-implemented method of claim 16, wherein outputting stored history data comprises exporting the stored history data to another computing device, i.e. display screen (Swedlow; Paragraph 0025).

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8. Claim 11 is rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Lisogurski (US 2011/0077473 A1) in view of Al-Ali (US 2008/0071153 A1), and further in view of Fouts (US Pat No. 5,692,505).

Regarding claim 11, the combination of Lisogurski and Al-Ali teaches the computer-implemented method of claim 10, but does not explicitly teach wherein the signal processing comprises determining a noise signal, removing the noise signal, and outputting the filtered data. Fouts, however, teaches a method of data processing for oximeters, wherein the signal processing comprises determining a noise signal present in the raw data and filtering the raw data to remove the noise signal (Fouts; Col. 7 Lines 34-43); and outputting the filtered raw data as filtered parameter data (Fouts; Col. 7 Lines 58-65). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to combine the method of the combination of Lisogurski and Al-Ali with the method of removing noise, as taught by Fouts, because noise signals are present in almost every raw physiological signals due to ambient light or motion artifact. Therefore, in order to improve accuracy of the physiological measurements, it would have been obvious to filter out the noise signal before outputting a measurement.

9. Claims 19-21 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Lisogurski (US 2011/0077473 A1) in view of Al-Ali (US 2008/0071153 A1), and further in view of Otto (US 2008/0211657 A1).

Regarding claim 19, the combination of Lisogurski and Al-Ali teaches the computer-implemented method of claim 10, but does not explicitly teach connecting to a network using the mobile computing device and transmitting the filtered parameter data over the network. Otto, however, teaches a wireless sensor network system, further comprising connecting to a network using the mobile computing device, i.e. controller (Otto; 102 in Fig. 1) and transmitting the

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parameter data over the network (Otto; Paragraphs 0031 and 0037). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide the method of the combination of Lisogurski and Al-Ali with a method of transmitting filtered physiological data over a network in order to allow wireless monitoring of patients in hospitals where clinicians need to monitor many different patients at the same time.

Regarding claim 20, the combination of Lisogurski, Al-Ali, and Otto teaches the computer-implemented method of claim 19, wherein the filtered parameter data is transmitted over the network to a calibration service, i.e. control logic in the controller (Otto; Paragraphs 0053 and 0066-0067), the method further comprising incorporating the filtered parameter data into a sensor data set (Otto; Paragraphs 0041-0042 and 0048). Although Otto does not explicitly teach incorporating filtered parameter data into a calibration data set, it would have been obvious to a person having ordinary skill in the art to incorporate filtered patient data into a calibration data set in order to configure the sensor specifically to the user that is using the sensor, especially since sensors can be used interchangeably by multiple patients at hospitals.

Regarding claim 21, the combination of Lisogurski, Al-Ali, and Otto teaches the computer-implemented method of claim 20, but does not explicitly teach further comprising using the calibration data set to generate a calibration curve. However, generating a calibration curve is a conventional method of graphically displaying the calibration data set. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to generate a calibration curve using the calibration data set of the combination of Lisogurski, Al-Ali, and Otto in order to make the calibration data set more easily-readable by the user or clinician as well as to easily monitor calibration trends.

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Response to Arguments

10. Applicant's arguments, filed 02/12/2016, with respect to specification objections have been fully considered and are persuasive. The objections of the present specification has been withdrawn.

11. Applicant's arguments with respect to 35 U.S.C. 112(f) claim interpretations of claims 1 and 2 have been fully considered and are persuasive. The 35 U.S.C. 112(f) claim interpretations of claims 1 and 2 have been withdrawn.

Applicant's arguments with respect to 35 U.S.C. 112(f) claim interpretation of claim 8, however, have been fully considered but they are not persuasive. Amended claim 8 recites "a processor configured to execute instructions for transmitting, via a network connection, the filtered parameter data..." Although the Applicant argued that "a processor" as opposed to "a network communication module" recites sufficient structure to achieve the function of transmitting filtered parameter data, the Examiner respectfully disagrees. A processor could be any type of computer software or firmware. Therefore, reciting "a processor" does not provide sufficient structure that achieves the function. It is suggested that the Applicant further amends the claim to recite a specific structure to the processor.

12. Applicant's arguments, filed 02/12/2016, with respect to 35 U.S.C. 101 rejection has been fully considered and are persuasive. The 35 U.S.C. 101 rejection, therefore, has been withdrawn.

13. Applicant's arguments with respect to 35 U.S.C. 102 and 103 rejections have been considered but are moot in view of the new grounds of rejection as necessitated by the amendments.

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Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to YOOJIN LEE whose telephone number is (571)270-7069. The examiner can normally be reached on MON-FRI: 8AM-5PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ROBERT (TSE) CHEN can be reached on 571-272-3672. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/YOOJIN LEE/
Examiner, Art Unit 3777

/TSE CHEN/
Supervisory Patent Examiner, Art Unit 3777

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REMARKS

In the present response, Applicant amends Claims 1, 8, and 10. No new matter is added by these amendments, which are supported by at least the claims as originally filed and paragraph [0039] of the Specification as originally filed. Accordingly, Claims 1-21 are submitted for further consideration in light of the amendments illustrated in the foregoing section “Amendments to the Claims” and the following remarks.

Claim Interpretation - 35 U.S.C. § 112 ¶ 6

Regarding the interpretation by the Office Action of Claim 8 under 35 U.S.C. 112 ¶ 6, Applicant traverses the rejection, and for the reasons set forth below Applicant disagrees that Claim 8 falls within the scope of 35 U.S.C. 112 ¶ 6, as a means plus function claim.

Without necessarily agreeing with the rejection but to advance prosecution, as indicated above, Applicant has amended Claim 8 to recite “a signal processor configured to transmit...”.

Per MPEP § 2181, “a claim limitation that does not use the term “means” or “step” will trigger the rebuttable presumption that 35 U.S.C. 112(f) ... does not apply... This strong presumption may be overcome if the claim limitation is shown to use a non-structural term that is “a nonce word or a verbal construct that is not recognized as the name of structure” but is merely a substitute for the term “means” associated with functional language.” Following this, MPEP § 2181 provides a three-prong analysis for determining whether 35 U.S.C. 112(f) should apply, each prong of which must be met to apply 35 U.S.C. 112(f) to a claim limitation.

The first prong of the three-prong analysis requires that “the claim limitation uses the term “means” or “step” or a term used as a substitute for “means” that is a generic placeholder (also called a nonce term or a non-structural term having no specific structural meaning) for performing the claimed function.” Providing clarity regarding what may or may not constitute a generic placeholder, MPEP § 2181 explains that “35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, paragraph 6 will not apply if persons of ordinary skill in the art reading the specification understand the term to have a sufficiently definite meaning as the name for the structure that performs the function, even when the term covers a broad class of structures or identifies the structures by their function.” MPEP § 2181 further explains that “[f]or a term to be considered a substitute for “means,” and lack sufficient structure for performing the function, it must serve as

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a generic placeholder and thus not limit the scope of the claim to any specific manner or structure for performing the claimed function.”

Applicant submits that the term “signal processor” as recited in Claim 8 is a structural term with a specific structural meaning understood to have sufficiently definite meaning by persons of ordinary skill in the art. Further, the term “signal processor” as recited in Claim 8 serves to limit the scope of the claim to a specific structure for performing the claimed function. Thus, Claim 8 fails the first prong of the three-prong analysis.

The third prong of the three-prong analysis requires that “the term “means” or “step” or the generic placeholder is not modified by sufficient structure, material, or acts for performing the claimed function.” MPEP § 2181. Applicant respectfully submits that the term “signal processor” as recited in Claim 8 recites sufficient structure to perform the recited functions without the need to resort to the specification for adequate understanding of the structure. Thus, Claim 8 also fails the third prong of the three-prong analysis.

Accordingly, Applicant submits that Claim 8 falls outside of the scope of 35 U.S.C. 112 ¶ 6.

Art-Based Rejections— 35 USC § 103

The Office Action rejected Claims 1-2, 4, 6-7, 9-10, and 12-14 under 35 U.S.C. § 103(a) as unpatentable over Lisogurski (US 2011/0077473) in view of Al-Ali (US 2008/0071153).

The Office Action rejects Claim 3 under 35 U.S.C. § 103(a) as allegedly unpatentable over Lisogurski and Al-Ali and further in view of Turricchia (US 2010/0198094).

The Office Action rejects Claim 5 under 35 U.S.C. § 103(a) as allegedly unpatentable over Lisogurski in view of Al-Ali (US 2011/0071370).

The Office Action rejects Claims 8 and 15-18 under 35 U.S.C. § 103(a) as allegedly unpatentable over Lisogurski in view of Swedlow (US 2006/0224059).

The Office Action rejects Claim 11 under 35 U.S.C. § 103(a) as allegedly unpatentable over Lisogurski in view of Fouts (US Pat. No. 5,692,505).

The Office Action rejects Claims 19-21 under 35 U.S.C. § 103(a) as allegedly unpatentable over Lisogurski in view of Otto (US 2008/0211657).

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Applicant respectfully traverses each rejection and each assertion regarding what the reference discloses, and Applicant does not acquiesce in the validity of the rejections. To expedite allowance of this application, however, Applicant has amended independent Claims 1 and 10. As discussed below, Applicant submits that all of the pending claims are allowable over the cited references.

Independent Claim 1

The physiological monitoring system of amended Claim 1 in part includes:

“a cable including:

a processing board configured to establish an electrical signal connection between the physiological sensor and the mobile computing device, wherein the processing board receives raw data representing the monitored one or more physiological parameters and performs signal processing to provide filtered parameter data to the mobile computing device,

a first portion of the cable coupled between the physiological sensor and the processing board, the first portion of the cable extending a first distance mechanically isolating the processing board from the physiological sensor, and

a second portion of the cable coupled between the processing board and the mobile computing device, the second portion of the cable extending a second distance, wherein the second distance is smaller than the first distance.”

Lisogurski teaches a sensor-monitor interconnection system 10 in which “sensor 14 may connect to the patient monitor 12 by way of the sensor-monitor intercommunication cable 20.” *Lisogurski*, ¶ [0028]. Lisogurski illustrates this in Figure 1, reproduced below. A “short analog cable 18 may include a sensor connector 22 that joins to a sensor-side cable connector 24 of the sensor-monitor intercommunication cable 20,” and cable 20 “may include the sensor-side cable connector 24... and a monitor-side cable connector 28.” *Lisogurski*, ¶ [0023]. Lisogurski teaches that “sensor-side cable connector may have the capability to determine physiological measurements from the digitized data, which may be transmitted over the digital cable 26.” *Lisogurski*, ¶ [0040].

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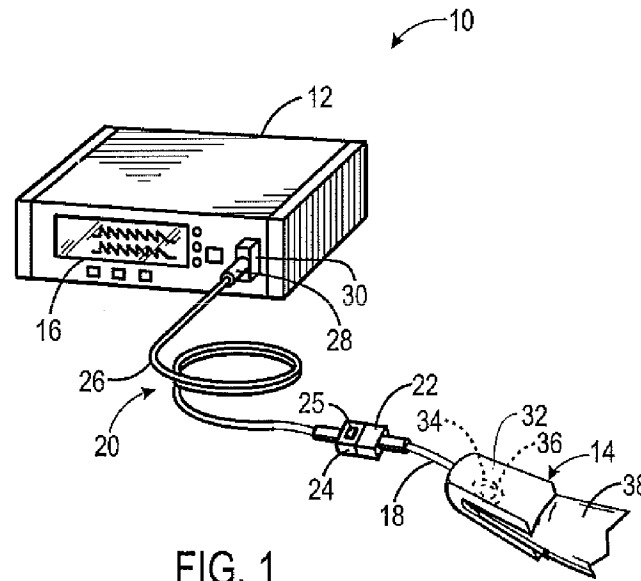


FIG. 1

Lisogurski, FIG 1

Lisogurski explicitly describes the “short analog cable 18” coupled between the sensor 14 and the connectors 22, 24, stating that “[t]he analog cable 18 may be of a sufficiently short length to prevent excessive interference before reaching the sensor-monitor intercommunication cable 20.” *Lisogurski*, ¶ [0025]. As illustrated in Figure 1, the cable 18 appears shorter even than the length of the sensor 14. Such a length would not mechanically isolate the connectors 22, 24 from movement of the sensor 14. As such, Lisogurski does not teach or suggest “a first portion of the cable coupled between the physiological sensor and the processing board, the first portion of the cable extending a first distance mechanically isolating the processing board from the physiological sensor.”

Further, in Figure 1 of Lisogurski the length of the digital cable 26 is many times greater than the length of the short analog cable 18. Accordingly, Lisogursky also does not teach or suggest “a second portion of the cable coupled between the processing board and the mobile computing device, the second portion of the cable extending a second distance, wherein the second distance is smaller than the first distance.”

Applicant respectfully submits that the cited portions of Al-Ali fail to cure the defects of Lisogurski described above.

For at least the foregoing reasons, Applicant respectfully submits that Lisogurski fails to teach each feature of Claim 1 as amended. Further, Applicant respectfully submits that the other

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art of record fails to remedy the defect of Lisogurski. Thus, Applicant requests that the rejection of Claim 1 under 35 U.S.C. § 103(a) be withdrawn.

Independent Claim 10

The method of amended Claim 10 in part includes:

“a cable including:

a processing board configured to establish an electrical signal connection between the sensor and a mobile computing device,

a first portion of the cable coupled between the physiological sensor and the processing board, the first portion of the cable extending a first distance mechanically isolating the processing board from the physiological sensor, and

a second portion of the cable coupled between the processing board and the mobile computing device, the second portion of the cable extending a second distance, wherein the second distance is smaller than the first distance”

For at least similar reasons to those discussed above with respect to Claim 1, the art of record fails to teach each feature of Claim 10 as amended. Thus, Applicant requests that the rejection of Claim 10 under 35 U.S.C. § 103(a) be withdrawn.

Discussion of Dependent Claims

Additionally, Applicant submits that the dependent claims also define over the cited references, not only because they depend from one of independent Claims 1 and 10, discussed above, but also on their own merit. Further, Applicant submits that the cited portions of Turricchia, Al-Ali, Swedlow, Fouts, and Otto fail to cure the defects of Lisogurski discussed above.

Thus, Applicant requests that all rejections under 35 U.S.C. § 102(b) and 35 U.S.C. § 103(a) be withdrawn.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicant is not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this

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Filing Date: September 20, 2013

application. Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

Conclusion

The Applicant has endeavored to address all of the Examiner's concerns as expressed in the outstanding Office Action. In view of the foregoing amendments and remarks, Applicant respectfully requests reconsideration and withdrawal of the outstanding rejections, and that the claims now be found in condition for allowance.

Any claim amendments which are not specifically discussed in the above remarks are not made for patentability purposes, and it is believed that the claims would satisfy the statutory requirements for patentability without the entry of such amendments. Rather, these amendments have only been made to increase claim readability, to improve grammar, and to reduce the time and effort required of those in the art to clearly understand the scope of the claim language.

Should the Examiner have any remaining concerns that might prevent the prompt allowance of the application, the Examiner is respectfully invited to contact the undersigned at the telephone number below.

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Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: August 29, 2016

By: /Lauren Hockett/

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AMENDMENTS TO THE CLAIMS

1. **(Currently Amended)** A physiological monitoring system comprising:
 - a physiological sensor configured to monitor one or more physiological parameters of a patient;
 - a mobile computing device comprising a display;
 - a cable including:
 - a processing board configured to establish an electrical signal connection between the physiological sensor and the mobile computing device, wherein the processing board receives raw data representing the monitored one or more physiological parameters and performs signal processing to provide filtered parameter data to the mobile computing device,
 - a first portion of the cable coupled between the physiological sensor and the processing board, the first portion of the cable extending a first distance mechanically isolating the processing board from the physiological sensor, and
 - a second portion of the cable coupled between the processing board and the mobile computing device, the second portion of the cable extending a second distance, wherein the second distance is smaller than the first distance; and
 - an enclosure comprising:
 - a body portion surrounding the processing board,
 - a first bend relief on a first side of the body portion, and
 - a second bend relief on a second side of the body portion, ~~[[a]]the~~ first portion of the cable coupled between the physiological sensor and the processing board through the first bend relief and ~~[[a]]the~~ second portion of the cable coupled between the processing board and the mobile computing device through the second bend relief.
2. **(Previously Presented)** The physiological monitoring system of claim 1, wherein the processing board is coupled to a port using a second portion of the cable, wherein the port is connectable to the mobile computing device.
3. **(Original)** The physiological monitoring system of claim 1, wherein the processing board comprises a digital processing board and an analog processing board.

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4. (Original) The physiological monitoring system of claim 1, wherein the processing board is in communication with an information element.

5. (Previously Presented) The physiological monitoring system of claim 1, wherein the mobile computing device provides a power signal to the processing board and the physiological sensor.

6. (Original) The physiological monitoring system of claim 1, wherein the mobile computing device presents the filtered parameter data to a user on the display.

7. (Original) The physiological monitoring system of claim 1, wherein the mobile computing device further comprises storage configured to store the filtered parameter data.

8. **(Currently Amended)** The physiological monitoring system of claim 1, wherein the mobile computing device further comprises a signal processor configured to transmit-execute instructions for transmitting, via a network connection, the filtered parameter data to at least one of a calibration service, a physician computing device, or a medical facility patient database.

9. (Previously Presented) The physiological monitoring system of claim 1, wherein the physiological sensor comprises one or more of a pulse oximeter, capnometer, capnograph, acoustic respiratory sensor, electroencephalograph, electrocardiograph, or temperature sensor.

10. **(Currently Amended)** A computer-implemented method of mobile physiological monitoring, the method comprising:

providing a portable physiological monitoring system comprising:

a physiological sensor configured to monitor one or more physiological parameters of a patient,

a cable including:

a processing board configured to establish an electrical signal connection between the sensor and a mobile computing device,

a first portion of the cable coupled between the physiological sensor and the processing board, the first portion of the cable extending a first distance mechanically isolating the processing board from the physiological sensor, and

a second portion of the cable coupled between the processing board and the mobile computing device, the second portion of the cable

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extending a second distance, wherein the second distance is smaller than the first distance, and

an enclosure comprising:

a body portion surrounding the processing board,

a first bend relief on a first side of the body portion, and

a second bend relief on a second side of the body portion, ~~[[a]]~~the first portion of the cable coupled between the physiological sensor and the processing board through the first bend relief and ~~[[a]]~~the second portion of the cable coupled between the processing board and the mobile computing device through the second bend relief;

generating raw data representing the monitored one or more physiological parameters using the physiological sensor;

receiving the raw data at the processing board via the first portion of the cable;

performing signal processing on the raw data using the processing board, wherein the signal processing generates filtered parameter data; and

transmitting the filtered parameter data via the second portion of the cable to the mobile computing device.

11. (Original) The computer-implemented method of claim 10, wherein the signal processing comprises:

determining a noise signal present in the raw data;

filtering the raw data to remove the noise signal; and

outputting the filtered raw data as filtered parameter data.

12. (Original) The computer-implemented method of claim 10, wherein the filtered parameter data comprises one or more of oxygen saturation, pulse rate, perfusion index, signal quality, oxygen content, carboxyhemoglobin, methemoglobin, and acoustic respiration rate.

13. (Original) The computer-implemented method of claim 10, wherein transmitting the filtered parameter data to the mobile computing device comprises transmitting the filtered parameter data through the cable and a connection port to the mobile computing device.

14. (Original) The computer-implemented method of claim 10, wherein transmitting the filtered parameter data to the mobile computing device comprises transmitting the filtered parameter data through the cable to a wireless communication module, wherein the filtered

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parameter data is transmitted wirelessly to the mobile computing device from the wireless communication module.

15. (Original) The computer-implemented method of claim 10, further comprising providing a mobile monitoring application configured to track and display the filtered parameter data.

16. (Original) The computer-implemented method of claim 15, wherein the mobile monitoring application is further configured to output stored history data representing filtered parameter data monitored over a period of time.

17. (Original) The computer-implemented method of claim 16, wherein outputting stored history data comprises presenting the stored history data to a user on a display of the mobile computing device.

18. (Original) The computer-implemented method of claim 16, wherein outputting stored history data comprises exporting the stored history data to another computing device.

19. (Original) The computer-implemented method of claim 10, further comprising:
connecting to a network using the mobile computing device; and
transmitting the filtered parameter data over the network.

20. (Original) The computer-implemented method of claim 19, wherein the filtered parameter data is transmitted over the network to a calibration service, the method further comprising incorporating the filtered parameter data into a calibration data set

21. (Original) The computer-implemented method of claim 20, further comprising using the calibration data set to generate a calibration curve.

MASIMO.925A

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor	:	Bilal Muhsin
App. No.	:	14/033315
Filed	:	September 20, 2013
For	:	PHYSIOLOGICAL MONITOR WITH MOBILE COMPUTING DEVICE CONNECTIVITY
Examiner	:	Lee, Yoojin
Art Unit	:	3777
Conf. No.	:	9323

RESPONSE TO FINAL OFFICE ACTION

Mail Stop RCE

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In response to the final Office Action of March 29, 2016, Applicant submits the following amendments and remarks in the above-identified application.

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Remarks begin on page 6 of this paper.

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DETAILED ACTION

Notice of Pre-AIA or AIA Status

1. The present application is being examined under the pre-AIA first to invent provisions.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 08/29/2016 has been entered.

Claim Rejections/Interpretations - 35 USC § 112

3. The following is a quotation of 35 U.S.C. 112(b):
(b) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

The following is a quotation of 35 U.S.C. 112 (pre-AIA), second paragraph:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 8 is rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor, or for pre-AIA the applicant regards as the invention.

Claim 8 recites “a signal processor configured to transmit” which is indefinite for failing to particularly point out the specific structure of a processor that allows the processor to transmit data. For instance, in the present specification, Paragraphs 0093 and 0094 recites different embodiments of a signal processor, such as a DSP, ASIC, FPGA, etc. However, the claims do

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not recite any structure regarding the signal processor. Therefore, claim 8 is indefinite because it does not specify the structural components of a signal processor. In addition, the drawings, i.e. Fig. 2 of the present application, only shows boxed representations of these processors/modules and, thus, a person having ordinary skill in the art would not be able to determine what type of signal processor the claims are referring to.

The following is a quotation of 35 U.S.C. 112(f):

(f) Element in Claim for a Combination. – An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

The following is a quotation of pre-AIA 35 U.S.C. 112, sixth paragraph:

An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

2. Claim limitations and “a signal processor configured to transmit” has/have been interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, because it uses/they use a generic placeholder “signal processor” coupled with functional language “configured to transmit” without reciting sufficient structure to achieve the function. Furthermore, the generic placeholder is not preceded by a structural modifier.

Since the claim limitation(s) invokes 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, claim(s) 8 has/have been interpreted to cover the corresponding structure described in the specification that achieves the claimed function, and equivalents thereof.

If applicant wishes to provide further explanation or dispute the examiner’s interpretation of the corresponding structure, applicant must identify the corresponding structure with reference to the specification by page and line number, and to the drawing, if any, by reference characters in response to this Office action.

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If applicant does not intend to have the claim limitation(s) treated under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, applicant may amend the claim(s) so that it/they will clearly not invoke 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, or present a sufficient showing that the claim recites/recite sufficient structure, material, or acts for performing the claimed function to preclude application of 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph.

For more information, see MPEP § 2173 *et seq.* and *Supplementary Examination Guidelines for Determining Compliance With 35 U.S.C. 112 and for Treatment of Related Issues in Patent Applications*, 76 FR 7162, 7167 (Feb. 9, 2011).

Claim Rejections - 35 USC § 103

3. The following is a quotation of pre-AIA 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-2, 4, 6-7, 9-10, and 12-14 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Lisogurski (US 2011/0077473 A1) in view of Al-Ali (US 2008/0071153 A1), and further in view of Telfort (US 2011/0209915 A1).

Regarding claim 1, Lisogurski teaches a physiological monitoring system comprising a physiological sensor configured to monitor one or more physiological parameters of a patient (Lisogurski; 14 in Fig. 1); a mobile computing device (Lisogurski; 12 in Fig. 1) comprising a display (Lisogurski; 16 in Fig. 1); and a cable including a processing board (Lisogurski; 20 in Fig. 1 and Paragraph 0040) configured to establish an electrical signal connection between the

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physiological sensor and the mobile computing device, wherein the processing board receives raw data representing the monitored one or more physiological parameters and performs signal processing to provide filtered parameter data to the mobile computing device (Lisogurski; Paragraph 0047); and an enclosure comprising a body portion (Lisogurski; 24 in Fig. 1) surrounding the processing board, i.e. “the microprocessor 56 is incorporated into the sensor-side cable connector 24” (Lisogurski; Paragraph 0040), a first portion of the cable (Lisogurski; 22 in Fig. 1) coupled between the physiological sensor (Lisogurski; 14 in Fig. 1) and the processing board (Lisogurski; Paragraph 0040 – processing board is incorporated in the connector) and a second portion of the cable (Lisogurski; 24 in Fig. 1) coupled between the processing board (Lisogurski; Paragraph 0040 – processing board is incorporated in the connector) and the mobile computing device (Lisogurski; 12 in Fig. 1). Although Lisogurski teaches structures that resemble a first bend relief on a first side of the body portion (Lisogurski; 22 in Fig. 1) and a second bend relief on a second side of the body portion (Lisogurski; 24 in Fig. 1), Lisogurski does not explicitly teach a first and second bend relief. Al-Ali, however, teaches a bend relief (Al-Ali; 1500 in Fig. 8C) on a first side of the body portion (Al-Ali; 1200 in Fig. 8C). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide the system of Lisogurski with a first bend relief on a first side of the body portion and a second bend relief on a second side of the body portion in order to protect the cable and cable wires proximate the body (Al-Ali; Paragraph 0039).

The combination of Lisogurski and Al-Ali still does not explicitly teach the first portion of the cable extending a first distance mechanically isolating the processing board from the physiological sensor, and the second portion of the cable extending a second distance, wherein the second distance is smaller than the first distance. Telfort, however, teaches a first portion of the cable (Telfort; 630a,b in Fig. 6A) coupled between the physiological sensor and the

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processing board (Telfort; 640 in Fig. 6A and Paragraph 0086), the first portion of the cable extending a first distance (Telfort; 1511 and 1517 in Fig. 15) mechanically isolating the processing board (Telfort; 1520 in Fig. 15) from the physiological sensor (Telfort; 1515 in Fig. 15), and a second portion of the cable (Telfort; 622 in Fig. 6A and 1522 in Fig. 15) coupled between the processing board (Telfort; 640 in Fig. 6A) and the mobile computing device (Telfort; Paragraphs 0085 and 0158), the second portion of the cable extending a second distance (Telfort; 1522 in Fig. 15), wherein the second distance is smaller than the first distance (Telfort; 1511 and 1517 in Fig. 15). Therefore, it would have been obvious to a person having ordinary skill in the art at the time of filing to provide a first distance longer than the second distance, as taught by Telfort, in order to enable greater patient comfort, as the patient can move more easily with a flexible, elongated cable attached (Telfort; Paragraph 0090).

Regarding claim 2, the combination of Lisogurski, Al-Ali, and Telfort teaches the physiological monitoring system of claim 1, wherein the processing board is coupled to a port (Lisogurski; 30 in Fig. 1) using a second portion of the cable (Lisogurski; 26 and 28 in Fig. 1), wherein the port is connectable to the mobile computing device (Lisogurski; 12 in Fig. 1).

Regarding claim 4, the combination of Lisogurski, Al-Ali, and Telfort teaches the physiological monitoring system of claim 1, wherein the processing board (Lisogurski; 56 in Fig.3) is in communication with an information element (Lisogurski; 48 in Fig. 3 and Paragraphs 0036 and 0038).

Regarding claim 6, the combination of Lisogurski, Al-Ali, and Telfort teaches the physiological monitoring system of claim 1, wherein the mobile computing device presents the filtered data to a user on the display (Lisogurski; Paragraph 0047).

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Regarding claim 7, the combination of Lisogurski, Al-Ali, and Telfort teaches the physiological monitoring system of claim 1, wherein the mobile computing device further comprises storage configured to store the filtered parameter data (Lisogurski; Paragraph 0038).

Regarding claim 9, the combination of Lisogurski, Al-Ali, and Telfort teaches the physiological monitoring system of claim 1, wherein the physiological sensor comprises one or more of a pulse oximeter, capnometer, capnograph, acoustic respiratory sensor, electroencephalograph, electrocardiograph, or temperature sensor (Lisogurski; Paragraph 0021).

Regarding claim 10, the combination of Lisogurski, Al-Ali, and Telfort teaches a computer-implemented method of mobile physiological monitoring, the method comprising providing a portable physiological monitoring system comprising a physiological sensor configured to monitor one or more physiological parameters of a patient (Lisogurski; 14 in Fig. 1), and a cable including: a processing board (Lisogurski; 20 in Fig. 1 and Paragraph 0040) configured to establish an electrical connection between the sensor and a mobile computing device (Lisogurski; Paragraph 0040), a first portion of the cable (Telfort; 630a,b in Fig. 6A) coupled between the physiological sensor and the processing board (Telfort; 640 in Fig. 6A and Paragraph 0086), the first portion of the cable extending a first distance (Telfort; 1511 and 1517 in Fig. 15) mechanically isolating the processing board (Telfort; 1520 in Fig. 15) from the physiological sensor (Telfort; 1515 in Fig. 15), and a second portion of the cable (Telfort; 622 in Fig. 6A and 1522 in Fig. 15) coupled between the processing board (Telfort; 640 in Fig. 6A) and the mobile computing device (Telfort; Paragraphs 0085 and 0158), the second portion of the cable extending a second distance (Telfort; 1522 in Fig. 15), wherein the second distance is smaller than the first distance (Telfort; 1511 and 1517 in Fig. 15), and an enclosure comprising: a body portion surrounding the processing board (Lisogurski; 24 in Fig. 1 and Paragraph 0040),

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a first bend relief (Al-Ali; 1500 in Fig. 8C) on a first side of the body portion (Lisogurski; 22 in Fig. 1 – see rejection for claim 1), and a second bend relief (Al-Ali; 1500 in Fig. 8C) on a second side of the body portion (Lisogurski; 24 in Fig. 1 - see rejection for claim 1), the first portion of the cable (Lisogurski; 22 in Fig. 1) coupled between the physiological sensor (Lisogurski; 14 in Fig. 1) and the processing board (Lisogurski; Paragraph 0040) through the first bend relief (Al-Ali; 1500 in Fig. 8C) and the second portion of the cable (Lisogurski; 24 in Fig. 1) coupled between the processing board (Lisogurski; Paragraph 0040) and the mobile computing device (Lisogurski; 12 in Fig. 1) through the second bend relief (Al-Ali; 1500 in Fig. 8C); generating raw data representing the monitored one or more physiological parameters using the sensor (Lisogurski; Paragraph 0046); receiving the raw data at the processing board (Lisogurski; Paragraph 0047); performing signal processing on the raw data using the processing board, wherein the signal processing generates filtered parameter data (Lisogurski; Paragraph 0047); and transmitting the filtered parameter data to the mobile computing device (Lisogurski; Paragraph 0047).

Regarding claim 12, the combination of Lisogurski, Al-Ali, and Telfort teaches the computer-implemented method of claim 10, wherein the filtered parameter data comprises pulse rate or oxygen saturation (Lisogurski; Paragraph 0047).

Regarding claim 13, the combination of Lisogurski, Al-Ali, and Telfort teaches the computer-implemented method of claim 10, wherein transmitting the filtered parameter data to the mobile computing device comprises transmitting the filtered parameter data through the cable (Lisogurski; 20 in Fig. 1) and a connection port (Lisogurski; 30 in Fig. 1) to the mobile computing device (Lisogurski; Paragraph 0047 and Fig. 6).

Regarding claim 14, the combination of Lisogurski, Al-Ali, and Telfort teaches the computer-implemented method of claim 10, wherein transmitting the filtered parameter data to

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the mobile computing device comprises transmitting the filtered parameter data through the cable to a wireless communication module (Lisogurski; 120 in Fig. 10), wherein the filtered parameter data is transmitted wirelessly to the mobile computing device from the wireless communication module (Lisogurski; Paragraph 0055 and Fig. 10).

5. Claim 3 is rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Lisogurski (US 2011/0077473 A1), Al-Ali (US 2008/0071153 A1), and Telfort (US 2011/0209915 A1), and further in view of Turicchia (US 2010/0198094 A1).

Regarding claim 3, the combination of Lisogurski, Al-Ali, and Telfort teaches the physiological monitoring system of claim 1, but does not explicitly teach wherein the processing board comprises both a digital processing board and an analog processing board. However, Turicchia teaches a wearable monitoring system, wherein the processing board comprises both a digital processing board and an analog processing board (Turicchia; Paragraph 0043). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide the system of the combination of Lisogurski, Al-Ali, and Telfort with an analog processor and a digital processor in order to receive and process physiological signals from monitoring sensors, and to trigger a visual or audible alarm in the event that a patient requires medical attention.

6. Claim 5 is rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Lisogurski (US 2011/0077473 A1), Al-Ali (US 2008/0071153 A1), and Telfort (US 2011/0209915 A1), and further in view of Al-Ali '370 (US 2011/0071370 A1).

Regarding claim 5, the combination of Lisogurski, Al-Ali, and Telfort teaches the physiological monitoring system of claim 1, but does not explicitly teach wherein the mobile

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computing device provides a power signal to the processing board and the sensor. Al-Ali '370, however, teaches a sensor module (Al-Ali '370; Fig. 6) wherein an external device provides a power signal to the processing board and the sensor (Al-Ali '370; Paragraph 0026). Although Al-Ali '370 does not explicitly teach a mobile computing device providing a power signal to the processing board and the sensor, it is conventional to connect a sensor via cable to a mobile computing device, i.e. monitor, in order to provide power to the sensor during operation. Also, incorporating portable batteries to a physiological sensor could be disadvantageous because the battery-life becomes significantly shorter and the sensor could stop taking measurements after a certain period of time. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide the system of the combination of Lisogurski, Al-Ali, and Telfort with a mobile computing device that provides a power signal to the processing board and the sensor in order to increase battery-life and to make sure the patient is continuously monitored even over a period of days.

7. Claims 8 and 15-18 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Lisogurski (US 2011/0077473 A1), Al-Ali (US 2008/0071153 A1), and Telfort (US 2011/0209915 A1), and further in view of Swedlow (US 2006/0224059 A1).

Regarding claim 8, the combination of Lisogurski, Al-Ali, and Telfort teaches the physiological monitoring system of claim 1, but does not explicitly teach wherein the mobile computing device further comprises a signal processor configured to transmit, via a network connection, the filtered parameter data to at least one of a calibration service, a physician computing device, or a medical facility patient database. Swedlow, however, teaches an oximeter system comprising a signal processor configured to transmit, via a network connection, the filtered parameter data to a medical facility patient database (Swedlow; Paragraphs 0028-

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0029). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide the system of the combination of Lisogurski, Al-Ali, and Telfort with a network communication module, as taught by Swedlow, in order to easily transmit stored patient information whenever a patient needs to be transferred to a different room in a hospital or a different medical facility.

Regarding claim 15, the combination of Lisogurski, Al-Ali, Telfort, and Swedlow teaches the computer-implemented method of claim 10, further comprising providing a mobile monitoring application, i.e. memory chip, configured to track and display the filtered parameter data (Swedlow; Paragraph 0025). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide the method of the combination of Lisogurski, Al-Ali, and Telfort with a mobile monitoring application, as taught by Swedlow, in order to monitor a trend in a patient's physiological condition in order to observe any health improvements or deterioration for diagnostic or therapeutic purposes.

Regarding claim 16, the combination of Lisogurski, Al-Ali, Telfort, and Swedlow teaches the computer-implemented method of claim 15, wherein the mobile monitoring application is further configured to output stored history data representing filtered parameter data monitored over a period of time (Swedlow; Paragraph 0026).

Regarding claim 17, the combination of Lisogurski, Al-Ali, Telfort, and Swedlow teaches the computer-implemented method of claim 16, wherein outputting stored history data comprises presenting the stored history data to a user on a display of the mobile computing device (Swedlow; Paragraph 0025).

Regarding claim 18, the combination of Lisogurski, Al-Ali, Telfort, and Swedlow teaches the computer-implemented method of claim 16, wherein outputting stored history data

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comprises exporting the stored history data to another computing device, i.e. display screen (Swedlow; Paragraph 0025).

8. Claim 11 is rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Lisogurski (US 2011/0077473 A1), Al-Ali (US 2008/0071153 A1), and Telfort (US 2011/0209915 A1), and further in view of Fouts (US Pat No. 5,692,505).

Regarding claim 11, the combination of Lisogurski, Al-Ali, and Telfort teaches the computer-implemented method of claim 10, but does not explicitly teach wherein the signal processing comprises determining a noise signal, removing the noise signal, and outputting the filtered data. Fouts, however, teaches a method of data processing for oximeters, wherein the signal processing comprises determining a noise signal present in the raw data and filtering the raw data to remove the noise signal (Fouts; Col. 7 Lines 34-43); and outputting the filtered raw data as filtered parameter data (Fouts; Col. 7 Lines 58-65). It would have been obvious to a person having ordinary skill in the art at the time of filing to combine the method of the combination of Lisogurski, Al-Ali, and Telfort with the method of removing noise, as taught by Fouts, because noise signals are present in almost every raw physiological signals due to ambient light or motion artifact. Therefore, in order to improve accuracy of the physiological measurements, it would have been obvious to filter out the noise signal before outputting a measurement.

9. Claims 19-21 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Lisogurski (US 2011/0077473 A1), Al-Ali (US 2008/0071153 A1), and Telfort (US 2011/0209915 A1), and further in view of Otto (US 2008/0211657 A1).

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Regarding claim 19, the combination of Lisogurski, Al-Ali, and Telfort teaches the computer-implemented method of claim 10, but does not explicitly teach connecting to a network using the mobile computing device and transmitting the filtered parameter data over the network. Otto, however, teaches a wireless sensor network system, further comprising connecting to a network using the mobile computing device, i.e. controller (Otto; 102 in Fig. 1) and transmitting the parameter data over the network (Otto; Paragraphs 0031 and 0037). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide the method of the combination of Lisogurski, Al-Ali, and Telfort with a method of transmitting filtered physiological data over a network in order to allow wireless monitoring of patients in hospitals where clinicians need to monitor many different patients at the same time.

Regarding claim 20, the combination of Lisogurski, Al-Ali, Telfort, and Otto teaches the computer-implemented method of claim 19, wherein the filtered parameter data is transmitted over the network to a calibration service, i.e. control logic in the controller (Otto; Paragraphs 0053 and 0066-0067), the method further comprising incorporating the filtered parameter data into a sensor data set (Otto; Paragraphs 0041-0042 and 0048). Although Otto does not explicitly teach incorporating filtered parameter data into a calibration data set, it would have been obvious to a person having ordinary skill in the art to incorporate filtered patient data into a calibration data set in order to configure the sensor specifically to the user that is using the sensor, especially since sensors can be used interchangeably by multiple patients at hospitals.

Regarding claim 21, the combination of Lisogurski, Al-Ali, Telfort, and Otto teaches the computer-implemented method of claim 20, but does not explicitly teach further comprising using the calibration data set to generate a calibration curve. However, generating a calibration curve is a conventional method of graphically displaying the calibration data set. Therefore, it

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would have been obvious to a person having ordinary skill in the art at the time the invention was made to generate a calibration curve using the calibration data set of the combination of Lisogurski, Al-Ali, Telfort, and Otto in order to make the calibration data set more easily-readable by the user or clinician as well as to easily monitor calibration trends.

Response to Arguments

10. Applicant's arguments with respect to 35 U.S.C. 112(f) claim interpretation of claim 8, have been fully considered but they are not persuasive. Amended claim 8 recites "a signal processor configured to transmit the filtered parameter data..." Although the Applicant argued that "a signal processor" as opposed to "a processor" recites sufficient structure to achieve the function of transmitting filtered parameter data, the Examiner respectfully disagrees. A signal processor could be any type of computer software or firmware. Even in the present specification, the Applicants disclose a range of different structures that a signal processor could be in Paragraphs 0093 and 0094. For example, the Applicants point out in the specification that a signal processor could be a DSP, ASIC, FPGA, etc. These specific structures are disclosed in the specification; however, the claims do not recite any of these specific structures. Therefore, reciting "a signal processor" does not provide sufficient structure that achieves the function, and is still considered a generic placeholder. It is suggested that the Applicant further amends the claim to recite a specific structure to the processor.

11. Applicant's arguments with respect to 35 U.S.C. 103 rejections have been considered but are moot in view of the new grounds of rejection as necessitated by the amendments.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to YOOJIN LEE whose telephone number is (571)270-7069. The examiner can normally be reached on MON-FRI: 8AM-5PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ROBERT (TSE) CHEN can be reached on 571-272-3672. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/YOOJIN LEE/
Examiner, Art Unit 3777

/TSE CHEN/
Supervisory Patent Examiner, Art Unit 3777

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REMARKS

In the present response, Applicant amends Claim 8. No new matter is added by these amendments, which are supported by at least the claims as originally filed and paragraph [0051] of the Specification as originally filed. Accordingly, Claims 1-21 are submitted for further consideration in light of the amendments illustrated in the foregoing section “Amendments to the Claims” and the following remarks.

Claim Interpretation - 35 U.S.C. § 112 ¶ 2

The Office Action rejects Claim 8 under 35 U.S.C. 112 ¶ 2 as allegedly indefinite, specifically because the specification recites different embodiments of a signal processor not recited by Claim 1. Applicant traverses the rejection, however as indicated above has amended Claim 8 to instead recite a “network connectivity module.” Thus, Applicant submits that the rejection of Claim 8 under 35 U.S.C. 112 ¶ 2 is moot and respectfully requests withdrawal of the same.

Claim Interpretation - 35 U.S.C. § 112 ¶ 6

Regarding the interpretation by the Office Action of Claim 8 under 35 U.S.C. 112 ¶ 6, Applicant notes that the phrase “signal processor” alleged in the Office Action to be a generic placeholder has been removed. Thus, Applicant submits that the interpretation of Claim 8 under 35 U.S.C. 112 ¶ 6 as presented in the Office Action is moot.

Art-Based Rejections— 35 USC § 103

The Office Action rejected Claims 1-2, 4, 6-7, 9-10, and 12-14 under 35 U.S.C. § 103(a) as unpatentable over Lisogurski (US 2011/0077473) in view of Al-Ali (US 2008/0071153) and further in view of Telfort (US 2011/0209915).

The Office Action rejects Claim 3 under 35 U.S.C. § 103(a) as allegedly unpatentable over Lisogurski, Al-Ali, and Telfort, and further in view of Turricchia (US 2010/0198094).

The Office Action rejects Claim 5 under 35 U.S.C. § 103(a) as allegedly unpatentable over Lisogurski, Al-Ali, and Telfort, and further in view of Al-Ali '370 (US 2011/0071370).

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The Office Action rejects Claims 8 and 15-18 under 35 U.S.C. § 103(a) as allegedly unpatentable over Lisogurski, Al-Ali, and Telfort, and further in view of Swedlow (US 2006/0224059).

The Office Action rejects Claim 11 under 35 U.S.C. § 103(a) as allegedly unpatentable over Lisogurski, Al-Ali, and Telfort, and further in view of (US Pat. No. 5,692,505).

The Office Action rejects Claims 19-21 under 35 U.S.C. § 103(a) as allegedly unpatentable over Lisogurski, Al-Ali, and Telfort, and further in view of Otto (US 2008/0211657).

Applicant respectfully traverses each rejection and each assertion regarding what the reference discloses, and Applicant does not acquiesce in the validity of the rejections. As discussed below, Applicant submits that all of the pending claims are allowable over the cited references.

Independent Claim 1

The physiological monitoring system of Claim 1 in part includes:

“a cable including:

a processing board configured to establish an electrical signal connection between the physiological sensor and the mobile computing device, wherein the processing board receives raw data representing the monitored one or more physiological parameters and performs signal processing to provide filtered parameter data to the mobile computing device,

a first portion of the cable coupled between the physiological sensor and the processing board, the first portion of the cable extending a first distance mechanically isolating the processing board from the physiological sensor, and

a second portion of the cable coupled between the processing board and the mobile computing device, the second portion of the cable extending a second distance, wherein the second distance is smaller than the first distance.”

The Office Action cites Lisogurski as teaching a first portion 22 of a cable coupled between a sensor 14 and a processing board and a second portion 24 coupled between the processing board and a mobile computing device 12. The Office Action cites Al-Ali as teaching a bend relief 1200. *Office Action*, pages 4-5.

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As acknowledged by the Office Action, “[t]he combination of Lisogurski and Al-Ali still does not explicitly teach the first portion of the cable extending a first distance mechanically isolating the processing board from the physiological sensor, and the second portion of the cable extending a second distance, wherein the second distance is smaller than the first distance.

The Office Action cites Telfort as allegedly teaching the features lacking in Lisogurski and Al-Ali. Even if Telfort taught or suggested these features, a point which Applicant does not concede, Applicant respectfully submits that the proposed modifications would frustrate the purpose of Lisogurski and there is no motivation to combine Lisogurski and Telfort.

Lisogurski teaches a sensor-monitor interconnection system 10 in which a “short analog cable 18 may include a sensor connector 22 that joins to a sensor-side cable connector 24 of the sensor-monitor intercommunication cable 20.” Lisogurski explicitly describes the reason for the length of the “short analog cable 18” coupled between the sensor 14 and the connectors 22, 24, stating that “[t]he analog cable 18 may be of a sufficiently short length to prevent excessive interference before reaching the sensor-monitor intercommunication cable 20.” *Lisogurski*, ¶ [0025]. As illustrated in Figure 1, reproduced below, the cable 18 is shorter even than the length of the sensor 14, and appears to be roughly the same length as the distal phalanx at the end of the finger of the patient 38 on which the sensor 14 is placed.

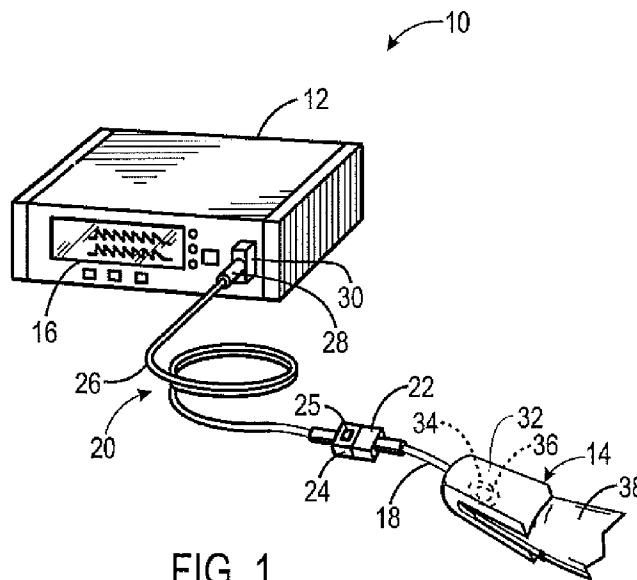


FIG. 1

Lisogurski, FIG 1

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Thus, Lisogurski requires that the cable 18 be very short to “prevent excessive interference” with the analog signal traveling along the cable 18. As such, Lisogurski teaches away from modifying the cable 18 to have a long length as shown in the long coiled cables 1517, 1511 of Telfort.

1. The Proposed Modifications Frustrate the Purpose of Lisogurski

M.P.E.P. § 2143.01(V) states “[i]f proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. In re Gordon, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984).” Here, lengthening the cable 18 of Lisogurski would frustrate the purpose of the Lisogurski system because the cable 18 is taught to be short to prevent interference with the analog signal, and is depicted as being far shorter even than the finger of the patient with which the Lisogursky sensor 32 is used.

As such, Applicant respectfully submits that a person of ordinary skill in the art would not have a reason to combine the cables of Telfort with the cable 18 of Lisogurski and that further, the combination thereof would frustrate the explicit purpose of Lisogurski to use the cable 18 to provide to provide the analog signal to the connector 22. Therefore, Applicant respectfully requests that the rejection be withdrawn.

2. Lisogurski Teaches Away from the Proposed Modifications

M.P.E.P. § 2143.03(VI) states that “[a] prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention.”

Lisogurski includes teachings that would lead the person of ordinary skill away from lengthening the cable 18. For example, Lisogurski explicitly describes the reason for the length of the “short analog cable 18” coupled between the sensor 14 and the connectors 22, 24, stating that “[t]he analog cable 18 may be of a sufficiently short length to prevent excessive interference before reaching the sensor-monitor intercommunication cable 20.” *Lisogurski*, ¶ [0025]. Therefore, the skilled person would not be motivated to modify this cable 18 to instead have an increased length.

Because Lisogurski teaches away from having a long cable 18, one of ordinary skill in the art would not modify Lisogurski to incorporate certain features of Telfort in an effort to arrive at the claimed invention.

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3. Conclusion

As discussed above, Lisogurski and Telfort are not combinable and Lisogurski teaches away from the modifications proposed in the Office Action.

As such, the skilled person would not combine Lisogurski with Telfort or any other reference to arrive at the claimed system having “a first portion of the cable coupled between the physiological sensor and the processing board, the first portion of the cable extending a first distance mechanically isolating the processing board from the physiological sensor” and “a second portion of the cable coupled between the processing board and the mobile computing device, the second portion of the cable extending a second distance, wherein the second distance is smaller than the first distance.”

Applicant respectfully submits that the cited portions of Al-Ali fail to cure the defects of Lisogurski and Telfort described above.

Thus, Applicant requests that the rejection of Claim 1 under 35 U.S.C. § 103(a) be withdrawn.

Independent Claim 10

The method of Claim 10 in part includes:

“a cable including:

a processing board configured to establish an electrical signal connection between the sensor and a mobile computing device,

a first portion of the cable coupled between the physiological sensor and the processing board, the first portion of the cable extending a first distance mechanically isolating the processing board from the physiological sensor, and

a second portion of the cable coupled between the processing board and the mobile computing device, the second portion of the cable extending a second distance, wherein the second distance is smaller than the first distance”

For at least similar reasons to those discussed above with respect to Claim 1, the art of record fails to teach each feature of Claim 10 as amended. Thus, Applicant requests that the rejection of Claim 10 under 35 U.S.C. § 103(a) be withdrawn.

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Discussion of Dependent Claims

Additionally, Applicant submits that the dependent claims also define over the cited references, not only because they depend from one of independent Claims 1 and 10, discussed above, but also on their own merit. Thus, Applicant requests that all rejections under 35 U.S.C. § 103(a) be withdrawn.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicant is not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

Conclusion

The Applicant has endeavored to address all of the Examiner's concerns as expressed in the outstanding Office Action. In view of the foregoing amendments and remarks, Applicant respectfully requests reconsideration and withdrawal of the outstanding rejections, and that the claims now be found in condition for allowance.

Any claim amendments which are not specifically discussed in the above remarks are not made for patentability purposes, and it is believed that the claims would satisfy the statutory requirements for patentability without the entry of such amendments. Rather, these amendments have only been made to increase claim readability, to improve grammar, and to reduce the time and effort required of those in the art to clearly understand the scope of the claim language.

Should the Examiner have any remaining concerns that might prevent the prompt allowance of the application, the Examiner is respectfully invited to contact the undersigned at the telephone number below.

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Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: March 15, 2017

By: /Lauren Hockett/

Lauren Hockett
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MASIMO.925A

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor	:	Bilal Muhsin
App. No.	:	14/033315
Filed	:	September 20, 2013
For	:	PHYSIOLOGICAL MONITOR WITH MOBILE COMPUTING DEVICE CONNECTIVITY
Examiner	:	Lee, Yoojin
Art Unit	:	3777
Conf. No.	:	9323

RESPONSE TO NON-FINAL OFFICE ACTION

Mail Stop Amendment

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Dear Sir:

In response to the non-final Office Action of September 16, 2016, Applicant submits the following amendments and remarks in the above-identified application.

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Remarks begin on page 6 of this paper.



UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/033,315	09/20/2013	Bilal Muhsin	MASIMO.925A	9323
64735 7590 04/19/2017 KNOBBE, MARTENS, OLSON & BEAR, LLP MASIMO CORPORATION (MASIMO) 2040 MAIN STREET FOURTEENTH FLOOR IRVINE, CA 92614			EXAMINER LEE, YOOJIN	
			ART UNIT	PAPER NUMBER
			3777	
			NOTIFICATION DATE	DELIVERY MODE
			04/19/2017	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jayna.cartee@knobbe.com
 efiling@knobbe.com

Office Action Summary	Application No. 14/033,315	Applicant(s) MUHSIN ET AL.	
	Examiner YOOJIN LEE	Art Unit 3777	AIA (First Inventor to File) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on 03/15/2017.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☒ Claim(s) 1-21 is/are pending in the application.
5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☒ Claim(s) 1-21 is/are rejected.

8) ☐ Claim(s) _____ is/are objected to.

9) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

10) ☐ The specification is objected to by the Examiner.

11) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a) ☐ All b) ☐ Some** c) ☐ None of the:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

2) ☐ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)
Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.

4) ☐ Other: _____.

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DETAILED ACTION

Notice of Pre-AIA or AIA Status

1. The present application is being examined under the pre-AIA first to invent provisions.

Claim Rejections/Interpretations - 35 USC § 112

2. The following is a quotation of 35 U.S.C. 112(b):
(b) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

The following is a quotation of 35 U.S.C. 112 (pre-AIA), second paragraph:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 8 is rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor, or for pre-AIA the applicant regards as the invention.

Claim 8 recites “a network connectivity module configured to transmit” which is indefinite for failing to particularly point out the specific structure of a processor that allows the processor to transmit data. For instance, in the present specification, Paragraphs 0029 and 0031 recites different embodiments of a network connectivity module such as “one or more of a cellular network, satellite network, Bluetooth, ZigBee, wireless network, wired network, etc. However, the *claims* do not recite any structure regarding the network connectivity module. Therefore, claim 8 is indefinite because it does not specify the structural components of a network connectivity module. Therefore, a person having ordinary skill in the art would not be able to determine what type of network connectivity module the claims are referring to.

The following is a quotation of 35 U.S.C. 112(f):

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(f) Element in Claim for a Combination. – An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

The following is a quotation of pre-AIA 35 U.S.C. 112, sixth paragraph:

An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

2. Claim limitations and “a network connectivity module configured to transmit” has/have been interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, because it uses/they use a generic placeholder “module” coupled with functional language “configured to transmit” without reciting sufficient structure to achieve the function. Furthermore, the generic placeholder is not preceded by a structural modifier.

Since the claim limitation(s) invokes 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, claim(s) 8 has/have been interpreted to cover the corresponding structure described in the specification that achieves the claimed function, and equivalents thereof.

If applicant wishes to provide further explanation or dispute the examiner’s interpretation of the corresponding structure, applicant must identify the corresponding structure with reference to the specification by page and line number, and to the drawing, if any, by reference characters in response to this Office action.

If applicant does not intend to have the claim limitation(s) treated under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, applicant may amend the claim(s) so that it/they will clearly not invoke 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, or present a sufficient showing that the claim recites/recite sufficient structure, material, or acts for performing the claimed function to preclude application of 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph.

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For more information, see MPEP § 2173 *et seq.* and *Supplementary Examination Guidelines for Determining Compliance With 35 U.S.C. 112 and for Treatment of Related Issues in Patent Applications*, 76 FR 7162, 7167 (Feb. 9, 2011).

Claim Rejections - 35 USC § 103

3. The following is a quotation of pre-AIA 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-2, 4, 6-7, 9-10, and 12-14 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Lisogurski (US 2011/0077473 A1) in view of Al-Ali (US 2008/0071153 A1), and further in view of Telfort (US 2011/0209915 A1).

Regarding claim 1, Lisogurski teaches a physiological monitoring system comprising a physiological sensor configured to monitor one or more physiological parameters of a patient (Lisogurski; 14 in Fig. 1); a mobile computing device (Lisogurski; 12 in Fig. 1) comprising a display (Lisogurski; 16 in Fig. 1); and a cable including a processing board (Lisogurski; 20 in Fig. 1 and Paragraph 0040) configured to establish an electrical signal connection between the physiological sensor and the mobile computing device, wherein the processing board receives raw data representing the monitored one or more physiological parameters and performs signal processing to provide filtered parameter data to the mobile computing device (Lisogurski; Paragraph 0047); and an enclosure comprising a body portion (Lisogurski; 24 in Fig. 1) surrounding the processing board, i.e. “the microprocessor 56 is incorporated into the sensor-side cable connector 24” (Lisogurski; Paragraph 0040), a first portion of the cable (Lisogurski;

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22 in Fig. 1) coupled between the physiological sensor (Lisogurski; 14 in Fig. 1) and the processing board (Lisogurski; Paragraph 0040 – processing board is incorporated in the connector) and a second portion of the cable (Lisogurski; 24 in Fig. 1) coupled between the processing board (Lisogurski; Paragraph 0040 – processing board is incorporated in the connector) and the mobile computing device (Lisogurski; 12 in Fig. 1). Although Lisogurski teaches structures that resemble a first bend relief on a first side of the body portion (Lisogurski; 22 in Fig. 1) and a second bend relief on a second side of the body portion (Lisogurski; 24 in Fig. 1), Lisogurski does not explicitly teach a first and second bend relief. Al-Ali, however, teaches a bend relief (Al-Ali; 1500 in Fig. 8C) on a first side of the body portion (Al-Ali; 1200 in Fig. 8C). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide the system of Lisogurski with a first bend relief on a first side of the body portion and a second bend relief on a second side of the body portion in order to protect the cable and cable wires proximate the body (Al-Ali; Paragraph 0039).

The combination of Lisogurski and Al-Ali still does not explicitly teach the first portion of the cable extending a first distance mechanically isolating the processing board from the physiological sensor, and the second portion of the cable extending a second distance, wherein the second distance is smaller than the first distance. Telfort, however, teaches a first portion of the cable (Telfort; 630a,b in Fig. 6A) coupled between the physiological sensor and the processing board (Telfort; 640 in Fig. 6A and Paragraph 0086), the first portion of the cable extending a first distance (Telfort; 1511 and 1517 in Fig. 15) mechanically isolating the processing board (Telfort; 1520 in Fig. 15) from the physiological sensor (Telfort; 1515 in Fig. 15), and a second portion of the cable (Telfort; 622 in Fig. 6A and 1522 in Fig. 15) coupled between the processing board (Telfort; 640 in Fig. 6A) and the mobile computing device (Telfort; Paragraphs 0085 and 0158), the second portion of the cable extending a second distance

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(Telfort; 1522 in Fig. 15), wherein the second distance is smaller than the first distance (Telfort; 1511 and 1517 in Fig. 15). Therefore, it would have been obvious to a person having ordinary skill in the art at the time of filing to provide a first distance longer than the second distance, as taught by Telfort, in order to enable greater patient comfort, as the patient can move more easily with a flexible, elongated cable attached (Telfort; Paragraph 0090).

Regarding claim 2, the combination of Lisogurski, Al-Ali, and Telfort teaches the physiological monitoring system of claim 1, wherein the processing board is coupled to a port (Lisogurski; 30 in Fig. 1) using a second portion of the cable (Lisogurski; 26 and 28 in Fig. 1), wherein the port is connectable to the mobile computing device (Lisogurski; 12 in Fig. 1).

Regarding claim 4, the combination of Lisogurski, Al-Ali, and Telfort teaches the physiological monitoring system of claim 1, wherein the processing board (Lisogurski; 56 in Fig.3) is in communication with an information element (Lisogurski; 48 in Fig. 3 and Paragraphs 0036 and 0038).

Regarding claim 6, the combination of Lisogurski, Al-Ali, and Telfort teaches the physiological monitoring system of claim 1, wherein the mobile computing device presents the filtered data to a user on the display (Lisogurski; Paragraph 0047).

Regarding claim 7, the combination of Lisogurski, Al-Ali, and Telfort teaches the physiological monitoring system of claim 1, wherein the mobile computing device further comprises storage configured to store the filtered parameter data (Lisogurski; Paragraph 0038).

Regarding claim 9, the combination of Lisogurski, Al-Ali, and Telfort teaches the physiological monitoring system of claim 1, wherein the physiological sensor comprises one or more of a pulse oximeter, capnometer, capnograph, acoustic respiratory sensor,

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electroencephalograph, electrocardiograph, or temperature sensor (Lisogurski; Paragraph 0021).

Regarding claim 10, the combination of Lisogurski, Al-Ali, and Telfort teaches a computer-implemented method of mobile physiological monitoring, the method comprising providing a portable physiological monitoring system comprising a physiological sensor configured to monitor one or more physiological parameters of a patient (Lisogurski; 14 in Fig. 1), and a cable including: a processing board (Lisogurski; 20 in Fig. 1 and Paragraph 0040) configured to establish an electrical connection between the sensor and a mobile computing device (Lisogurski; Paragraph 0040), a first portion of the cable (Telfort; 630a,b in Fig. 6A) coupled between the physiological sensor and the processing board (Telfort; 640 in Fig. 6A and Paragraph 0086), the first portion of the cable extending a first distance (Telfort; 1511 and 1517 in Fig. 15) mechanically isolating the processing board (Telfort; 1520 in Fig. 15) from the physiological sensor (Telfort; 1515 in Fig. 15), and a second portion of the cable (Telfort; 622 in Fig. 6A and 1522 in Fig. 15) coupled between the processing board (Telfort; 640 in Fig. 6A) and the mobile computing device (Telfort; Paragraphs 0085 and 0158), the second portion of the cable extending a second distance (Telfort; 1522 in Fig. 15), wherein the second distance is smaller than the first distance (Telfort; 1511 and 1517 in Fig. 15), and an enclosure comprising: a body portion surrounding the processing board (Lisogurski; 24 in Fig. 1 and Paragraph 0040), a first bend relief (Al-Ali; 1500 in Fig. 8C) on a first side of the body portion (Lisogurski; 22 in Fig. 1 – see rejection for claim 1), and a second bend relief (Al-Ali; 1500 in Fig. 8C) on a second side of the body portion (Lisogurski; 24 in Fig. 1 - see rejection for claim 1), the first portion of the cable (Lisogurski; 22 in Fig. 1) coupled between the physiological sensor (Lisogurski; 14 in Fig. 1) and the processing board (Lisogurski; Paragraph 0040) through the first bend relief (Al-Ali; 1500 in Fig. 8C) and the second portion of the cable (Lisogurski; 24 in Fig. 1) coupled between

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the processing board (Lisogurski; Paragraph 0040) and the mobile computing device (Lisogurski; 12 in Fig. 1) through the second bend relief (Al-Ali; 1500 in Fig. 8C); generating raw data representing the monitored one or more physiological parameters using the sensor (Lisogurski; Paragraph 0046); receiving the raw data at the processing board (Lisogurski; Paragraph 0047); performing signal processing on the raw data using the processing board, wherein the signal processing generates filtered parameter data (Lisogurski; Paragraph 0047); and transmitting the filtered parameter data to the mobile computing device (Lisogurski; Paragraph 0047).

Regarding claim 12, the combination of Lisogurski, Al-Ali, and Telfort teaches the computer-implemented method of claim 10, wherein the filtered parameter data comprises pulse rate or oxygen saturation (Lisogurski; Paragraph 0047).

Regarding claim 13, the combination of Lisogurski, Al-Ali, and Telfort teaches the computer-implemented method of claim 10, wherein transmitting the filtered parameter data to the mobile computing device comprises transmitting the filtered parameter data through the cable (Lisogurski; 20 in Fig. 1) and a connection port (Lisogurski; 30 in Fig. 1) to the mobile computing device (Lisogurski; Paragraph 0047 and Fig. 6).

Regarding claim 14, the combination of Lisogurski, Al-Ali, and Telfort teaches the computer-implemented method of claim 10, wherein transmitting the filtered parameter data to the mobile computing device comprises transmitting the filtered parameter data through the cable to a wireless communication module (Lisogurski; 120 in Fig. 10), wherein the filtered parameter data is transmitted wirelessly to the mobile computing device from the wireless communication module (Lisogurski; Paragraph 0055 and Fig. 10).

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5. Claim 3 is rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Lisogurski (US 2011/0077473 A1), Al-Ali (US 2008/0071153 A1), and Telfort (US 2011/0209915 A1), and further in view of Turicchia (US 2010/0198094 A1).

Regarding claim 3, the combination of Lisogurski, Al-Ali, and Telfort teaches the physiological monitoring system of claim 1, but does not explicitly teach wherein the processing board comprises both a digital processing board and an analog processing board. However, Turicchia teaches a wearable monitoring system, wherein the processing board comprises both a digital processing board and an analog processing board (Turicchia; Paragraph 0043). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide the system of the combination of Lisogurski, Al-Ali, and Telfort with an analog processor and a digital processor in order to receive and process physiological signals from monitoring sensors, and to trigger a visual or audible alarm in the event that a patient requires medical attention.

6. Claim 5 is rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Lisogurski (US 2011/0077473 A1), Al-Ali (US 2008/0071153 A1), and Telfort (US 2011/0209915 A1), and further in view of Al-Ali '370 (US 2011/0071370 A1).

Regarding claim 5, the combination of Lisogurski, Al-Ali, and Telfort teaches the physiological monitoring system of claim 1, but does not explicitly teach wherein the mobile computing device provides a power signal to the processing board and the sensor. Al-Ali '370, however, teaches a sensor module (Al-Ali '370; Fig. 6) wherein an external device provides a power signal to the processing board and the sensor (Al-Ali '370; Paragraph 0026). Although Al-Ali '370 does not explicitly teach a mobile computing device providing a power signal to the processing board and the sensor, it is conventional to connect a sensor via cable to a mobile

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computing device, i.e. monitor, in order to provide power to the sensor during operation. Also, incorporating portable batteries to a physiological sensor could be disadvantageous because the battery-life becomes significantly shorter and the sensor could stop taking measurements after a certain period of time. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide the system of the combination of Lisogurski, Al-Ali, and Telfort with a mobile computing device that provides a power signal to the processing board and the sensor in order to increase battery-life and to make sure the patient is continuously monitored even over a period of days.

7. Claims 8 and 15-18 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Lisogurski (US 2011/0077473 A1), Al-Ali (US 2008/0071153 A1), and Telfort (US 2011/0209915 A1), and further in view of Swedlow (US 2006/0224059 A1).

Regarding claim 8, the combination of Lisogurski, Al-Ali, and Telfort teaches the physiological monitoring system of claim 1, but does not explicitly teach wherein the mobile computing device further comprises a network connectivity module configured to transmit, via a network connection, the filtered parameter data to at least one of a calibration service, a physician computing device, or a medical facility patient database. Swedlow, however, teaches an oximeter system comprising a network connectivity module configured to transmit, via a network connection, the filtered parameter data to a medical facility patient database (Swedlow; 128 in Fig. 1, Paragraphs 0013, 0020-0021, 0028-0029). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide the system of the combination of Lisogurski, Al-Ali, and Telfort with a network communication module, as taught by Swedlow, in order to easily transmit stored patient information whenever a patient needs to be transferred to a different room in a hospital or a different medical facility.

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Regarding claim 15, the combination of Lisogurski, Al-Ali, Telfort, and Swedlow teaches the computer-implemented method of claim 10, further comprising providing a mobile monitoring application, i.e. memory chip, configured to track and display the filtered parameter data (Swedlow; Paragraph 0025). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide the method of the combination of Lisogurski, Al-Ali, and Telfort with a mobile monitoring application, as taught by Swedlow, in order to monitor a trend in a patient's physiological condition in order to observe any health improvements or deterioration for diagnostic or therapeutic purposes.

Regarding claim 16, the combination of Lisogurski, Al-Ali, Telfort, and Swedlow teaches the computer-implemented method of claim 15, wherein the mobile monitoring application is further configured to output stored history data representing filtered parameter data monitored over a period of time (Swedlow; Paragraph 0026).

Regarding claim 17, the combination of Lisogurski, Al-Ali, Telfort, and Swedlow teaches the computer-implemented method of claim 16, wherein outputting stored history data comprises presenting the stored history data to a user on a display of the mobile computing device (Swedlow; Paragraph 0025).

Regarding claim 18, the combination of Lisogurski, Al-Ali, Telfort, and Swedlow teaches the computer-implemented method of claim 16, wherein outputting stored history data comprises exporting the stored history data to another computing device, i.e. display screen (Swedlow; Paragraph 0025).

8. Claim 11 is rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Lisogurski (US 2011/0077473 A1), Al-Ali (US 2008/0071153 A1), and Telfort (US 2011/0209915 A1), and further in view of Fouts (US Pat No. 5,692,505).

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Regarding claim 11, the combination of Lisogurski, Al-Ali, and Telfort teaches the computer-implemented method of claim 10, but does not explicitly teach wherein the signal processing comprises determining a noise signal, removing the noise signal, and outputting the filtered data. Fouts, however, teaches a method of data processing for oximeters, wherein the signal processing comprises determining a noise signal present in the raw data and filtering the raw data to remove the noise signal (Fouts; Col. 7 Lines 34-43); and outputting the filtered raw data as filtered parameter data (Fouts; Col. 7 Lines 58-65). It would have been obvious to a person having ordinary skill in the art at the time of filing to combine the method of the combination of Lisogurski, Al-Ali, and Telfort with the method of removing noise, as taught by Fouts, because noise signals are present in almost every raw physiological signals due to ambient light or motion artifact. Therefore, in order to improve accuracy of the physiological measurements, it would have been obvious to filter out the noise signal before outputting a measurement.

9. Claims 19-21 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Lisogurski (US 2011/0077473 A1), Al-Ali (US 2008/0071153 A1), and Telfort (US 2011/0209915 A1), and further in view of Otto (US 2008/0211657 A1).

Regarding claim 19, the combination of Lisogurski, Al-Ali, and Telfort teaches the computer-implemented method of claim 10, but does not explicitly teach connecting to a network using the mobile computing device and transmitting the filtered parameter data over the network. Otto, however, teaches a wireless sensor network system, further comprising connecting to a network using the mobile computing device, i.e. controller (Otto; 102 in Fig. 1) and transmitting the parameter data over the network (Otto; Paragraphs 0031 and 0037). It would have been obvious to a person having ordinary skill in the art at the time the invention

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was made to provide the method of the combination of Lisogurski, Al-Ali, and Telfort with a method of transmitting filtered physiological data over a network in order to allow wireless monitoring of patients in hospitals where clinicians need to monitor many different patients at the same time.

Regarding claim 20, the combination of Lisogurski, Al-Ali, Telfort, and Otto teaches the computer-implemented method of claim 19, wherein the filtered parameter data is transmitted over the network to a calibration service, i.e. control logic in the controller (Otto; Paragraphs 0053 and 0066-0067), the method further comprising incorporating the filtered parameter data into a sensor data set (Otto; Paragraphs 0041-0042 and 0048). Although Otto does not explicitly teach incorporating filtered parameter data into a calibration data set, it would have been obvious to a person having ordinary skill in the art to incorporate filtered patient data into a calibration data set in order to configure the sensor specifically to the user that is using the sensor, especially since sensors can be used interchangeably by multiple patients at hospitals.

Regarding claim 21, the combination of Lisogurski, Al-Ali, Telfort, and Otto teaches the computer-implemented method of claim 20, but does not explicitly teach further comprising using the calibration data set to generate a calibration curve. However, generating a calibration curve is a conventional method of graphically displaying the calibration data set. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to generate a calibration curve using the calibration data set of the combination of Lisogurski, Al-Ali, Telfort, and Otto in order to make the calibration data set more easily-readable by the user or clinician as well as to easily monitor calibration trends.

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Response to Arguments

10. Applicant's arguments with respect to 35 U.S.C. 112(b) and 112(f) claim rejection/interpretation of claim 8, have been fully considered but are moot in view of the new grounds of rejection as necessitated by the amendments.

11. Applicant's arguments with respect to 35 U.S.C. 103 rejections have been fully considered but are not persuasive. The Applicants argued that combining the teachings of Lisogurski with the teachings of Telfort would frustrate the purpose of Lisogurski because Lisogurski teaches away from the proposed modifications. The Applicants cited Paragraph 0025 of Lisogurski, which states that "the analog cable 18 may be of *sufficiently short length* to prevent excessive interference before reaching the sensor-monitor intercommunication cable 20." Therefore, the Applicants argued that lengthening the analog cable 18 of Lisogurski would frustrate the purpose of preventing excessive interference. The Examiner respectfully disagrees. First, Lisogurski teaches that the cable 18 may be of "sufficiently short length" but does not specify how short the length of the cable needs to be in order to sufficiently prevent excessive interference. In the same way, claim 1 of the present application does not specify a value of a "first distance" that is capable of "mechanically isolating the processing board from the physiological sensor." Claim 1 merely states that the second distance is smaller than the first distance. With that said, the Examiner has relied on Telfort to teach a second portion with a second distance that is smaller than the first distance (Telfort; 1511 and 1522 in Fig. 15). In Figure 15 of Telfort, one can see that a second portion of the cable 1522 is significantly shorter than the sensor-side of the cable 1511. Therefore, modifying the teachings of Lisogurski to have a second portion of the cable that is shorter than the first portion of the cable, as taught by Telfort, would not necessarily result in first portion of the cable that is as long as the cable 1511

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in Fig. 15. Instead, a modification could be made to shorten the second portion of the cable 20 of Lisogurski in order to make cable 20 shorter than cable 18, as taught by Telfort. In that case, the combination of Lisogurski and Telfort teaches "a first portion of the cable extending a first distance mechanically isolating the processing board from the physiological sensor, and a... second portion of the cable extending a second distance, wherein the second distance is smaller than the first distance" without frustrating the purpose of Lisogurski. Therefore, at least for the foregoing reasons, the Applicant's arguments are not persuasive and do not place the application in condition for allowance.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to YOOJIN LEE whose telephone number is (571)270-7069. The examiner can normally be reached on MON-FRI: 8AM-5PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ROBERT (TSE) CHEN can be reached on 571-272-3672. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/YOOJIN LEE/
Examiner, Art Unit 3777

/TSE CHEN/
Supervisory Patent Examiner, Art Unit 3777

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REMARKS

In the present response, Applicant amends Claim 8. No new matter is added by these amendments, which are supported by at least the claims as originally filed and paragraph [0051] of the Specification as originally filed. Accordingly, Claims 1-21 are submitted for further consideration in light of the amendments illustrated in the foregoing section “Amendments to the Claims” and the following remarks.

Claim Interpretation - 35 U.S.C. § 112 ¶ 2

The Office Action rejects Claim 8 under 35 U.S.C. 112 ¶ 2 as allegedly indefinite, specifically because “it does not specify the structural components of a network connectivity module.” Applicant traverses the rejection, however as indicated above has amended Claim 8 to remove the recitation of the “network connectivity module.” Thus, Applicant submits that the rejection of Claim 8 under 35 U.S.C. 112 ¶ 2 is moot and respectfully requests withdrawal of the same.

Claim Interpretation - 35 U.S.C. § 112 ¶ 6

Regarding the interpretation by the Office Action of Claim 8 under 35 U.S.C. 112 ¶ 6, Applicant notes that the phrase “network connectivity module” alleged in the Office Action to be a generic placeholder has been removed. Thus, Applicant submits that the interpretation of Claim 8 under 35 U.S.C. 112 ¶ 6 as presented in the Office Action is moot.

Art-Based Rejections— 35 USC § 103

The Office Action rejected Claims 1-2, 4, 6-7, 9-10, and 12-14 under 35 U.S.C. § 103(a) as unpatentable over Lisogurski (US 2011/0077473) in view of Al-Ali (US 2008/0071153) and further in view of Telfort (US 2011/0209915).

The Office Action rejects Claim 3 under 35 U.S.C. § 103(a) as allegedly unpatentable over Lisogurski, Al-Ali, and Telfort, and further in view of Turricchia (US 2010/0198094).

The Office Action rejects Claim 5 under 35 U.S.C. § 103(a) as allegedly unpatentable over Lisogurski, Al-Ali, and Telfort, and further in view of Al-Ali '370 (US 2011/0071370).

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The Office Action rejects Claims 8 and 15-18 under 35 U.S.C. § 103(a) as allegedly unpatentable over Lisogurski, Al-Ali, and Telfort, and further in view of Swedlow (US 2006/0224059).

The Office Action rejects Claim 11 under 35 U.S.C. § 103(a) as allegedly unpatentable over Lisogurski, Al-Ali, and Telfort, and further in view of (US Pat. No. 5,692,505).

The Office Action rejects Claims 19-21 under 35 U.S.C. § 103(a) as allegedly unpatentable over Lisogurski, Al-Ali, and Telfort, and further in view of Otto (US 2008/0211657).

Applicant respectfully traverses each rejection and each assertion regarding what the reference discloses, and Applicant does not acquiesce in the validity of the rejections. As discussed below, Applicant submits that all of the pending claims are allowable over the cited references.

Independent Claim 1

The physiological monitoring system of Claim 1 in part includes:

“a cable including:

a processing board configured to establish an electrical signal connection between the physiological sensor and the mobile computing device, wherein the processing board receives raw data representing the monitored one or more physiological parameters and performs signal processing to provide filtered parameter data to the mobile computing device,

a first portion of the cable coupled between the physiological sensor and the processing board, the first portion of the cable extending a first distance mechanically isolating the processing board from the physiological sensor, and

a second portion of the cable coupled between the processing board and the mobile computing device, the second portion of the cable extending a second distance, wherein the second distance is smaller than the first distance.”

The Office Action cites Lisogurski as teaching a first portion 22 of a cable coupled between a sensor 14 and a processing board and a second portion 24 coupled between the processing board and a mobile computing device 12. The Office Action cites Al-Ali as teaching a bend relief 1200. *Office Action*, pages 4-5.

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As acknowledged by the Office Action, “[t]he combination of Lisogurski and Al-Ali still does not explicitly teach the first portion of the cable extending a first distance mechanically isolating the processing board from the physiological sensor, and the second portion of the cable extending a second distance, wherein the second distance is smaller than the first distance.

The Office Action cites Telfort as allegedly teaching the features lacking in Lisogurski and Al-Ali. Even if Telfort taught or suggested these features, a point which Applicant does not concede, Applicant respectfully submits that the proposed modifications would frustrate the purpose of Lisogurski and there is no motivation to combine Lisogurski and Telfort.

Lisogurski teaches a sensor-monitor interconnection system 10 in which a “short analog cable 18 may include a sensor connector 22 that joins to a sensor-side cable connector 24 of the sensor-monitor intercommunication cable 20.” Lisogurski explicitly describes the reason for the length of the “short analog cable 18” coupled between the sensor 14 and the connectors 22, 24, stating that “[t]he analog cable 18 may be of a sufficiently short length to prevent excessive interference before reaching the sensor-monitor intercommunication cable 20.” *Lisogurski*, ¶ [0025]. Thus, Lisogurski requires that the cable 18 be very short to “prevent excessive interference” with the analog signal traveling along the cable 18.

1. Lisogurski Teaches Away from the Proposed Modifications

M.P.E.P. § 2143.03(VI) states that “[a] prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention.”

Lisogurski includes teachings that would lead the person of ordinary skill away from lengthening the cable 18. For example, Lisogurski explicitly describes the reason for the length of the “short analog cable 18” coupled between the sensor 14 and the connectors 22, 24, stating that “[t]he analog cable 18 may be of a sufficiently short length to prevent excessive interference before reaching the sensor-monitor intercommunication cable 20.” *Lisogurski*, ¶ [0025]. Therefore, the skilled person would not be motivated to modify this cable 18 to instead have an increased length.

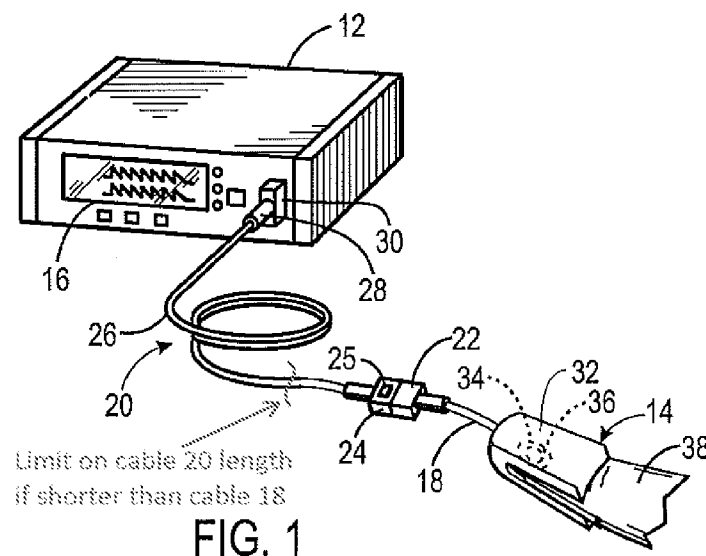
In response to these previously-submitted remarks, the Office Action indicates that “modifying the teachings of Lisogurski to have a second portion of the cable that is shorter than the first portion of the cable, as taught by Telfort, would not necessarily result in” a lengthened first portion of the cable, but “[i]nstead, a modification could be made to shorten the second

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portion of the cable 20 of Lisogurski in order to make cable 20 shorter than cable 18.” *Office Action*, pages 14-15. Applicant respectfully disagrees.

In addition to expressly teaching away from lengthening the “short analog cable 18” as described above, Lisogurski implicitly teaches away from shortening the cable 20. For example, Lisogurski teaches that the “cable 20 may include the sensor-side cable connector 24, a monitor protocol selection button or switch 25, intercommunication cabling 26, and a monitor-side cable connector 28.” *Lisogurski*, ¶ [0025]. Of these many different components that make up the cable 20, Lisogurski teaches that cable 26 includes “power, such as a 5V supply 66 in one particular embodiment, a ground line 68, and one or more digital communication lines 70” and carries “signals over the longest distance of the sensor-monitor intercommunication cable.” *Lisogurski*, ¶¶ [0041]-[0042]. Applicant respectfully submits that these teachings in Lisogurski regarding the length of cable 26 of the cable 20, as well as the teachings of the various components included along the length of the cable 20, the skilled person reading Lisogurski would lead the person of ordinary skill away from shortening the cable 20.

As illustrated in Figure 1, reproduced below and annotated below, the “short analog cable 18” is shorter even than the length of the sensor 14, and appears to be roughly the same length as the distal phalanx at the end of the finger of the patient 38 on which the sensor 14 is placed. Shortening the cable 20 to have a shorter length than the “short analog cable 18” as shown via the annotations below results in placement of the patient monitor 12 in extremely close proximity to the sensor 14 attached to the patient 38.



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Lisogurski, FIG 1, annotations added

As shown by the annotated limit on the length of cable 20, the overall length of the entire shortened cable (including cables 18 and 20 as well as connector 22) appears to be around the length of the illustrated finger of the patient 38. Applicant submits respectfully that this close positioning of the monitor 12 and the patient 38 would be impractical in the “hospital environments” of Lisogurski because it would require the monitor to be placed right next to the portion of the body of the patient 38 to which sensor 14 is attached. This impracticality is highlighted by the disclosure of Lisogurski that “[m]ulti-parameter patient monitors... display such patient parameters from a number of supported sensor types... [and] employ[s] a proprietary connector for each sensor type,” providing the example that “within a single electronic patient monitor, a first OEM module from a first manufacturer may receive a raw signal from a photoplethysmographic sensor... [and a] second OEM module from a different manufacturer may receive a raw signal from a blood pressure cuff.” *See, for example, Lisogurski*, ¶¶ [0003]-[0004]. Accordingly, this additional disclosure, viewed together with the cable lengths shown in Figure 1, further teaches away from shortening cable 20.

Because Lisogurski teaches away from lengthening cable 18 and away from shortening cable 20, one of ordinary skill in the art would not modify Lisogurski to incorporate certain features of Telfort in an effort to arrive at the claimed invention.

2. The Combination of Lisogurski and Telfort is Based on Impermissible Hindsight

As discussed above, shortening the cable 20 to be shorter than the “short analog cable 18” of Lisogurski would result in a placement of the monitor 12 in extremely close proximity to the patient 38. With respect to the combination of Lisogurski and Telfort, the Office Action alleges that “it would have been obvious to a person having ordinary skill in the art at the time of filing to provide a first distance longer than the second distance, as taught by Telfort, in order to enable greater patient comfort, as the patient can move more easily with a flexible, elongated cable attached,” pointing to Telfort, paragraph [0090]. *Office Action*, page 6.

However, based on the reasoning set forth in the Office Action, the skilled person would not be led to shorten the cable 20 of Lisogurski because this would result in an extremely short cable that has approximately the length of the finger of the patient, and thus shortening cable 20 would not result in “greater patient comfort, as the patient can move more easily with a flexible, elongated cable attached” as claimed in the Office Action. Further, the cited portion of Telfort

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does not relate to an elongated length of the cable as proffered by the Office Action, but rather to the weight and flexibility of the cable – “The flexible nature of the cable section 732 in one embodiment is provided to enable greater patient comfort, as the patient can move more easily with a flexible sensor cable 712 attached.” *Telfort*, ¶ [0090]. *See also*, *Telfort*, ¶ [0040] (“the lightweight, flexible characteristics of the sensor cable 112 make the sensor cable 112 more comfortable to attach to a patient”), ¶ [0088] (“the sensor cable 712 is a **short, lightweight cable**, adapted to facilitate comfortable attachment of sensors to a medical patient” (emphasis added)).

Indeed, the motivation to shorten the cable 20 as suggested by the Office Action is absent from the cited art and is only present in Applicant’s own specification, which describes at paragraph [0039] that “the second distance can be smaller than the first distance, placing the processing module 130 closer to the connection port 150 than to the sensor 110. This prevents the weight of the processing module 130 from interfering with or pulling on the sensor 110.” Due to the lack of motivation in the cited art to shorten the length of the cable 20 and the fact that such motivation is only present on the record in Applicant’s own specification, it logically follows that the concept of shortening the cable 20 of Lisogurski has been improperly gleaned from Applicant’s own specification. Therefore, the combination of Lisogurski and Telfort is based on impermissible hindsight. Accordingly, it is respectfully submitted that the combination is improper and respectfully requested that the rejection be withdrawn.

3. Conclusion

As discussed above, Lisogurski teaches away from the modifications proposed in the Office Action. Further, there is no motivation in the record, absent Applicant’s own specification, to modify Lisogurski as proposed in the Office Action.

As such, the skilled person would not combine Lisogurski with Telfort or any other reference to arrive at the claimed system having “a first portion of the cable coupled between the physiological sensor and the processing board, the first portion of the cable extending a first distance mechanically isolating the processing board from the physiological sensor” and “a second portion of the cable coupled between the processing board and the mobile computing device, the second portion of the cable extending a second distance, wherein the second distance is smaller than the first distance.”

Applicant respectfully submits that the cited portions of Al-Ali fail to cure the defects of Lisogurski and Telfort described above.

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Thus, Applicant requests that the rejection of Claim 1 under 35 U.S.C. § 103(a) be withdrawn.

Independent Claim 10

The method of Claim 10 in part includes:

“a cable including:

a processing board configured to establish an electrical signal connection between the sensor and a mobile computing device,

a first portion of the cable coupled between the physiological sensor and the processing board, the first portion of the cable extending a first distance mechanically isolating the processing board from the physiological sensor, and

a second portion of the cable coupled between the processing board and the mobile computing device, the second portion of the cable extending a second distance, wherein the second distance is smaller than the first distance”

For at least similar reasons to those discussed above with respect to Claim 1, the art of record fails to teach each feature of Claim 10 as amended. Thus, Applicant requests that the rejection of Claim 10 under 35 U.S.C. § 103(a) be withdrawn.

Discussion of Dependent Claims

Additionally, Applicant submits that the dependent claims also define over the cited references, not only because they depend from one of independent Claims 1 and 10, discussed above, but also on their own merit. Thus, Applicant requests that all rejections under 35 U.S.C. § 103(a) be withdrawn.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicant is not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution.

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Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

Conclusion

The Applicant has endeavored to address all of the Examiner's concerns as expressed in the outstanding Office Action. In view of the foregoing amendments and remarks, Applicant respectfully requests reconsideration and withdrawal of the outstanding rejections, and that the claims now be found in condition for allowance.

Any claim amendments which are not specifically discussed in the above remarks are not made for patentability purposes, and it is believed that the claims would satisfy the statutory requirements for patentability without the entry of such amendments. Rather, these amendments have only been made to increase claim readability, to improve grammar, and to reduce the time and effort required of those in the art to clearly understand the scope of the claim language.

Should the Examiner have any remaining concerns that might prevent the prompt allowance of the application, the Examiner is respectfully invited to contact the undersigned at the telephone number below.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: June 16, 2017

By: /Lauren Hockett/

Lauren Hockett
Registration No. 72,865
Attorney of Record
Customer No. 64735
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EXHIBIT 11



US 20080071153A1

(19) **United States**(12) **Patent Application Publication****Al-Ali et al.**(10) **Pub. No.: US 2008/0071153 A1**(43) **Pub. Date: Mar. 20, 2008**(54) **DUO CONNECTOR PATIENT CABLE****Publication Classification**

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Kevin Forest, Rancho Santa Margarita,
 CA (US)

(51) **Int. Cl.**
A61B 5/00 (2006.01)

(52) **U.S. Cl.** **600/310**

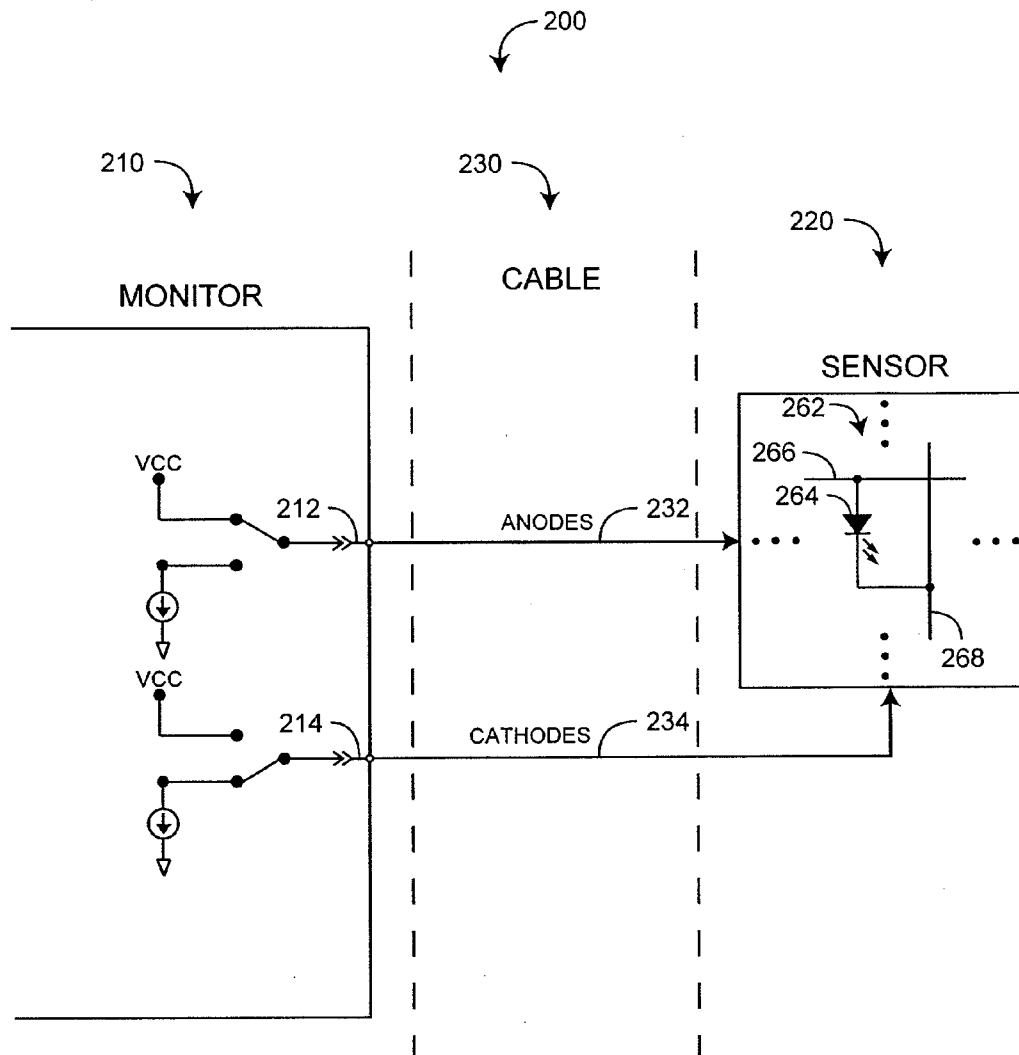
Correspondence Address:

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2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614 (US)

(57) **ABSTRACT**(21) Appl. No.: **11/858,818**(22) Filed: **Sep. 20, 2007****Related U.S. Application Data**

(60) Provisional application No. 60/846,260, filed on Sep. 20, 2006.

A patient cable has a duo sensor connector having a first socket section and a second socket section. The first socket section is configured to removably attach a two-wavelength sensor. The second socket section in conjunction with the first socket section is configured to removably attach a multiple wavelength sensor in lieu of the two-wavelength sensor. A circuit housed in the duo sensor connector converts emitter array drive signals adapted for the multiple wavelength sensor into back-to-back emitter drive signals adapted for the two-wavelength sensor when attached.



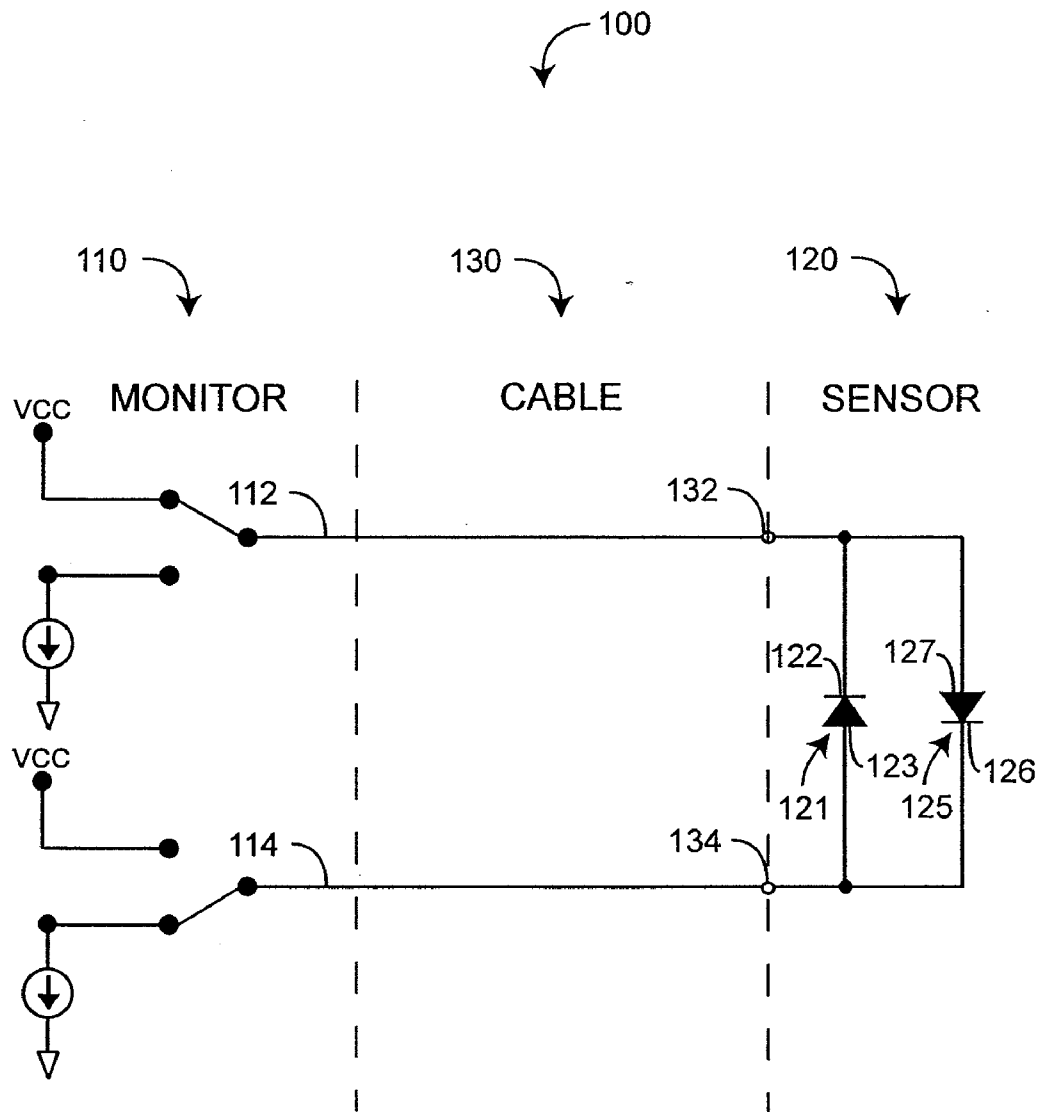


FIG. 1 (Prior Art)

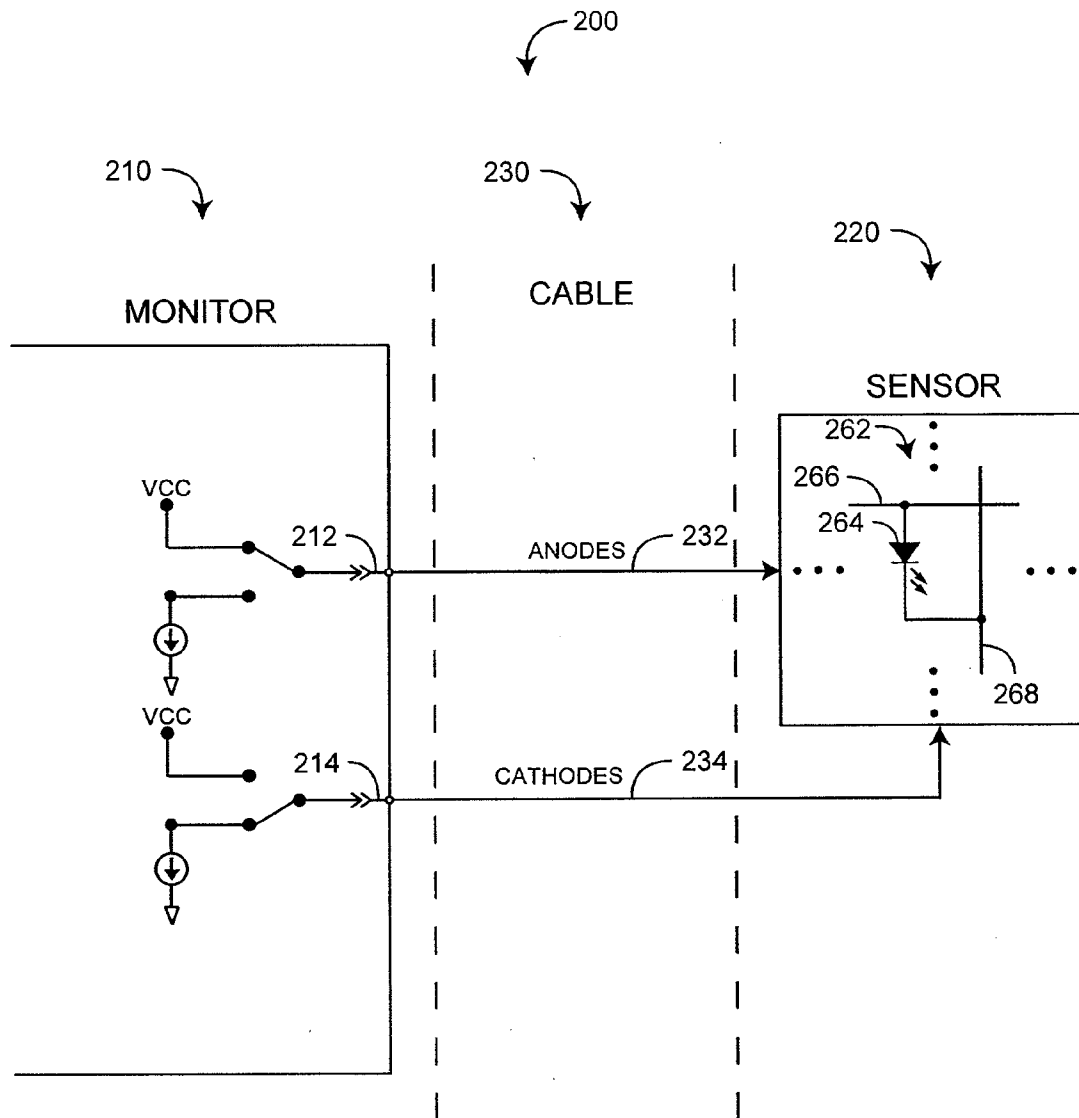


FIG. 2

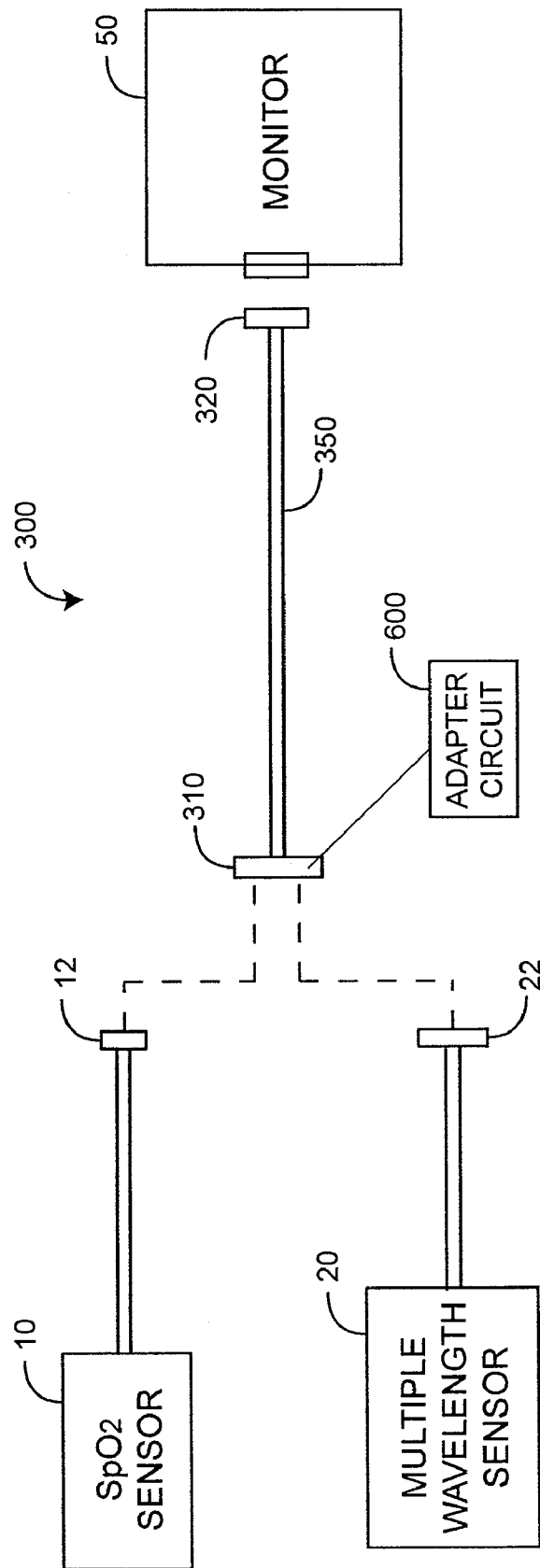


FIG. 3A

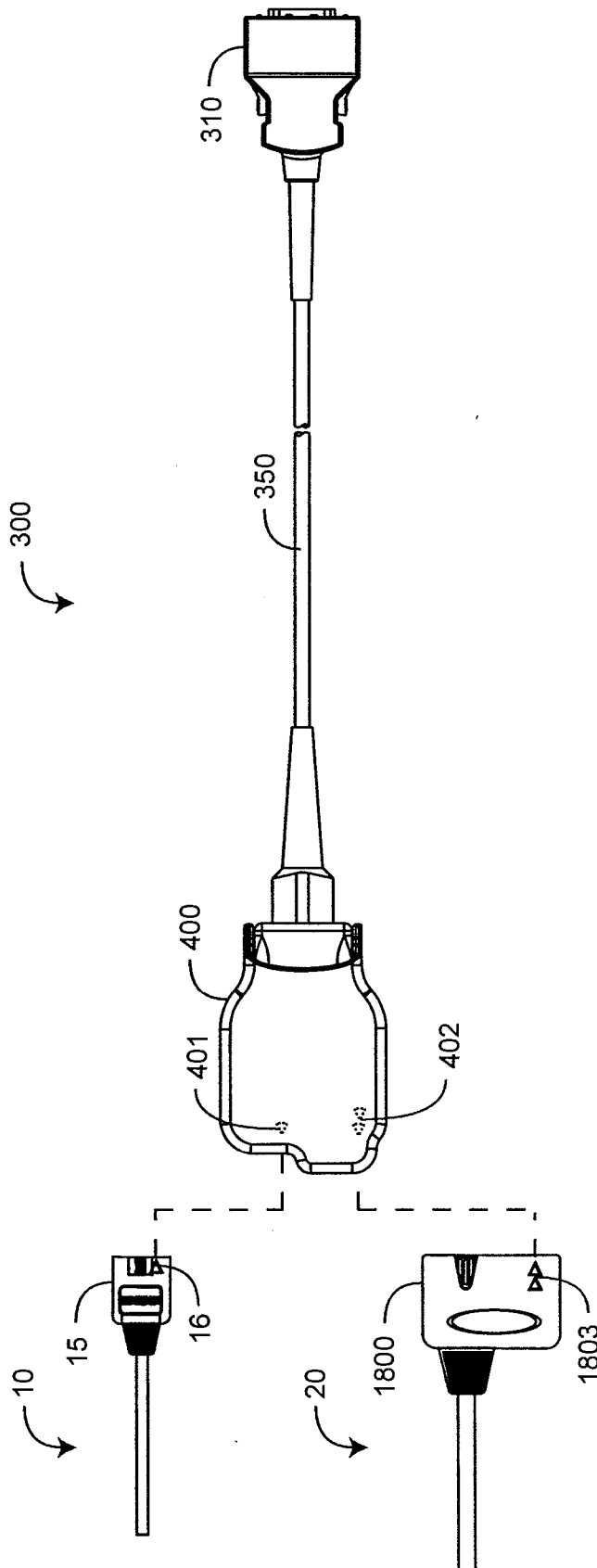


FIG. 3B

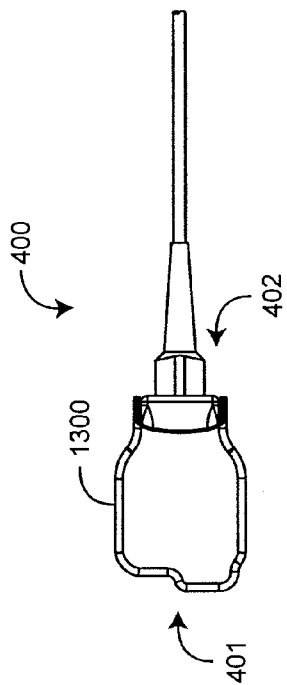


FIG. 4B

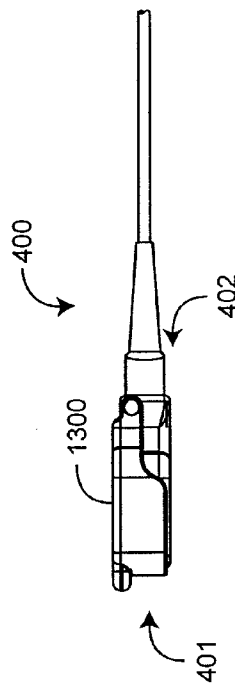


FIG. 4D

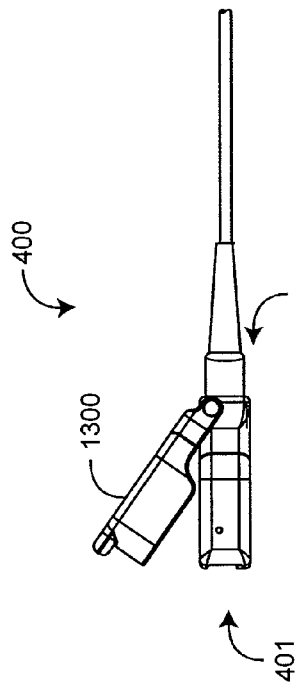


FIG. 4F

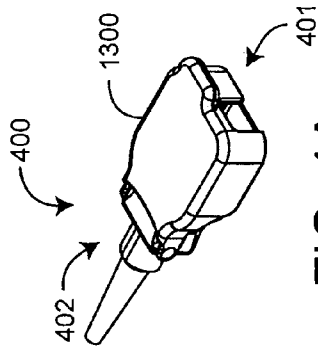


FIG. 4A

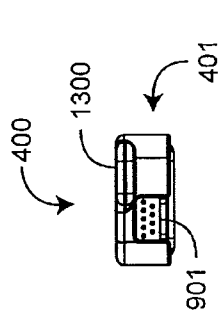


FIG. 4C

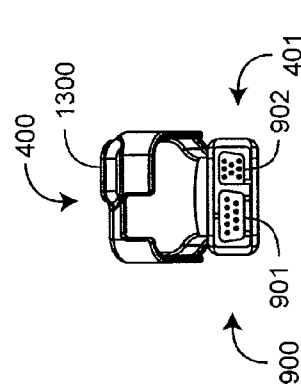


FIG. 4E

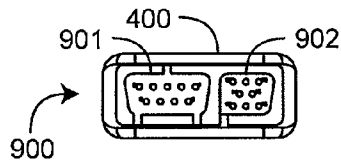


FIG. 5A

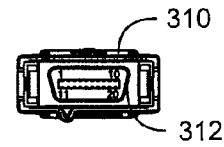


FIG. 5B

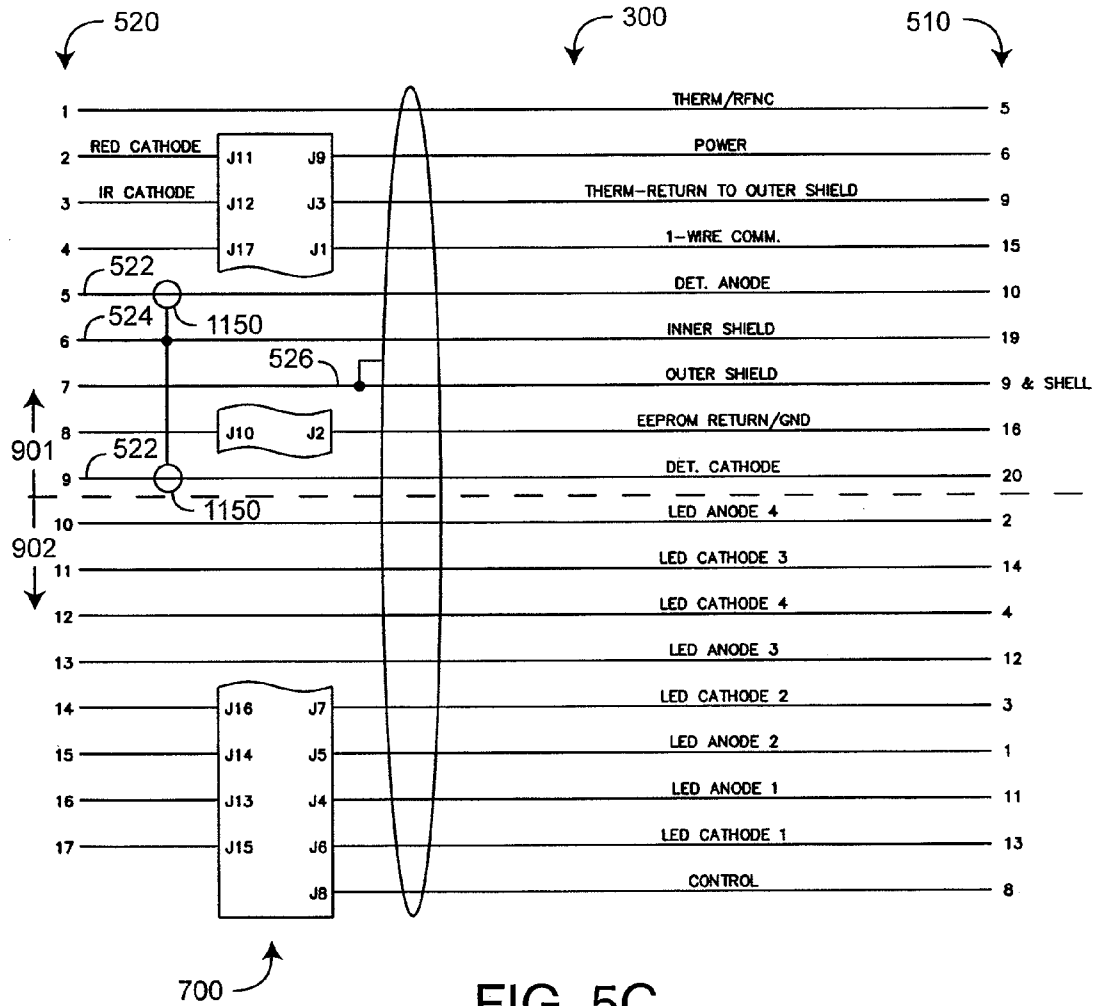


FIG. 5C

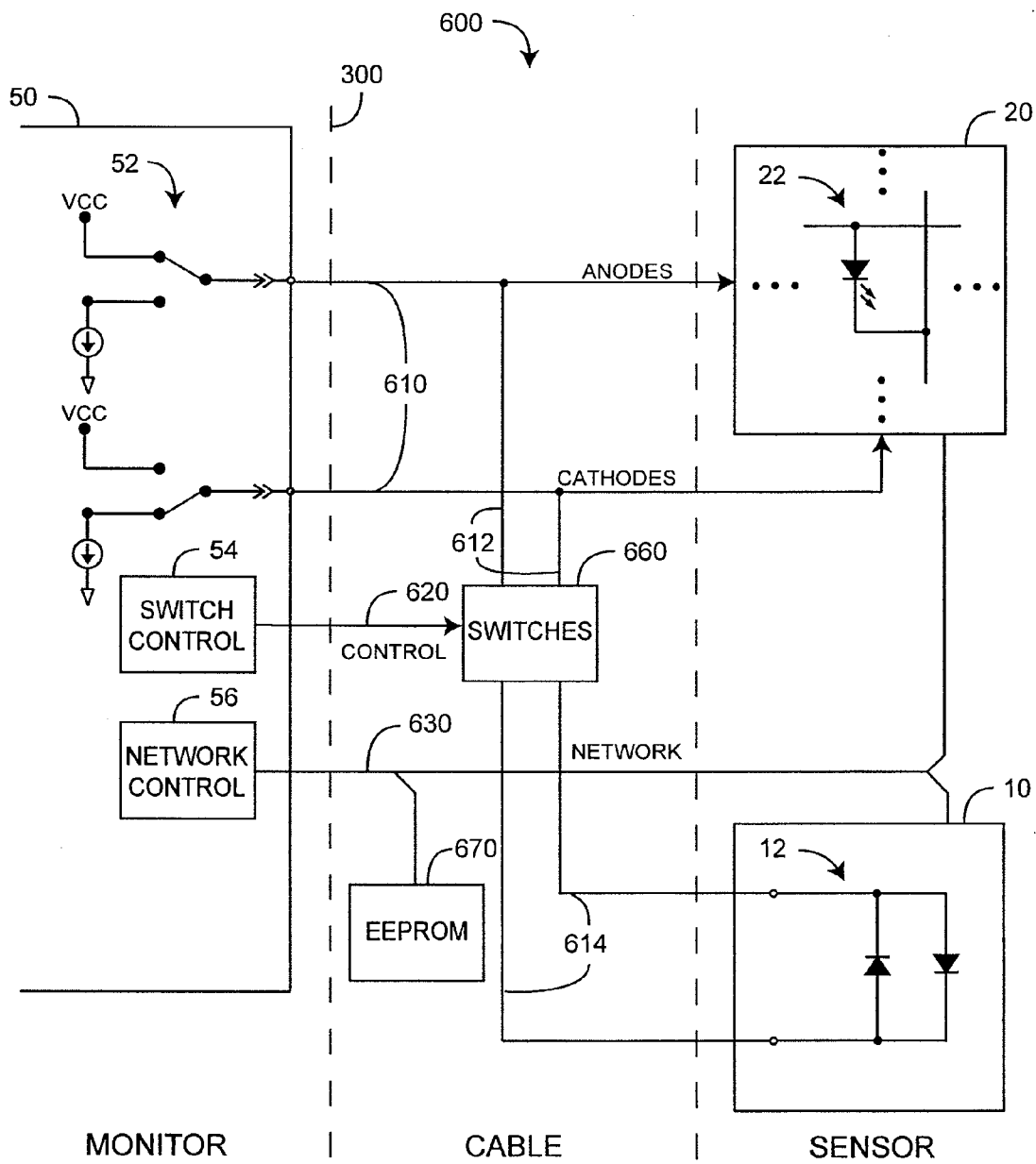


FIG. 6

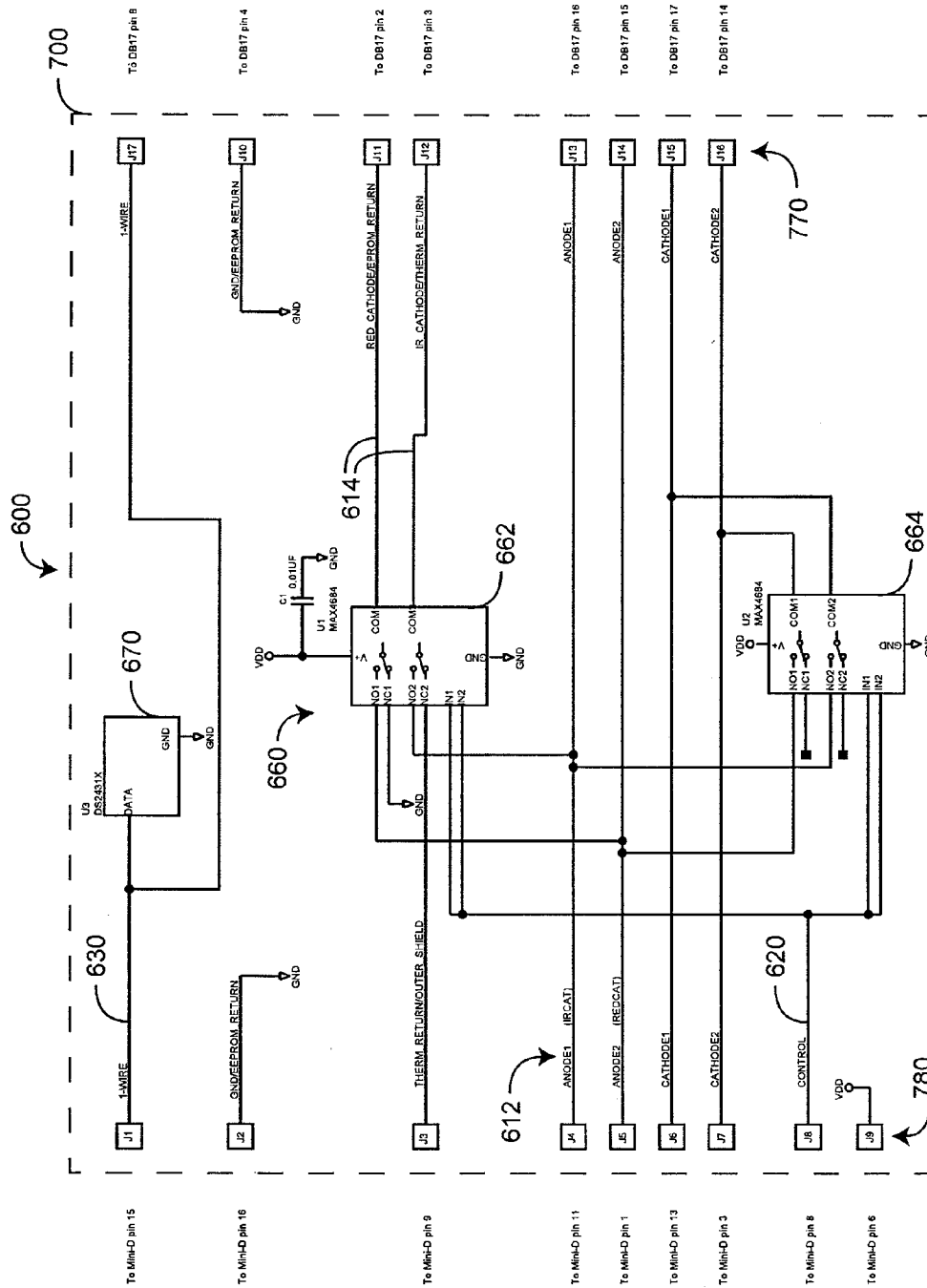


FIG. 7A

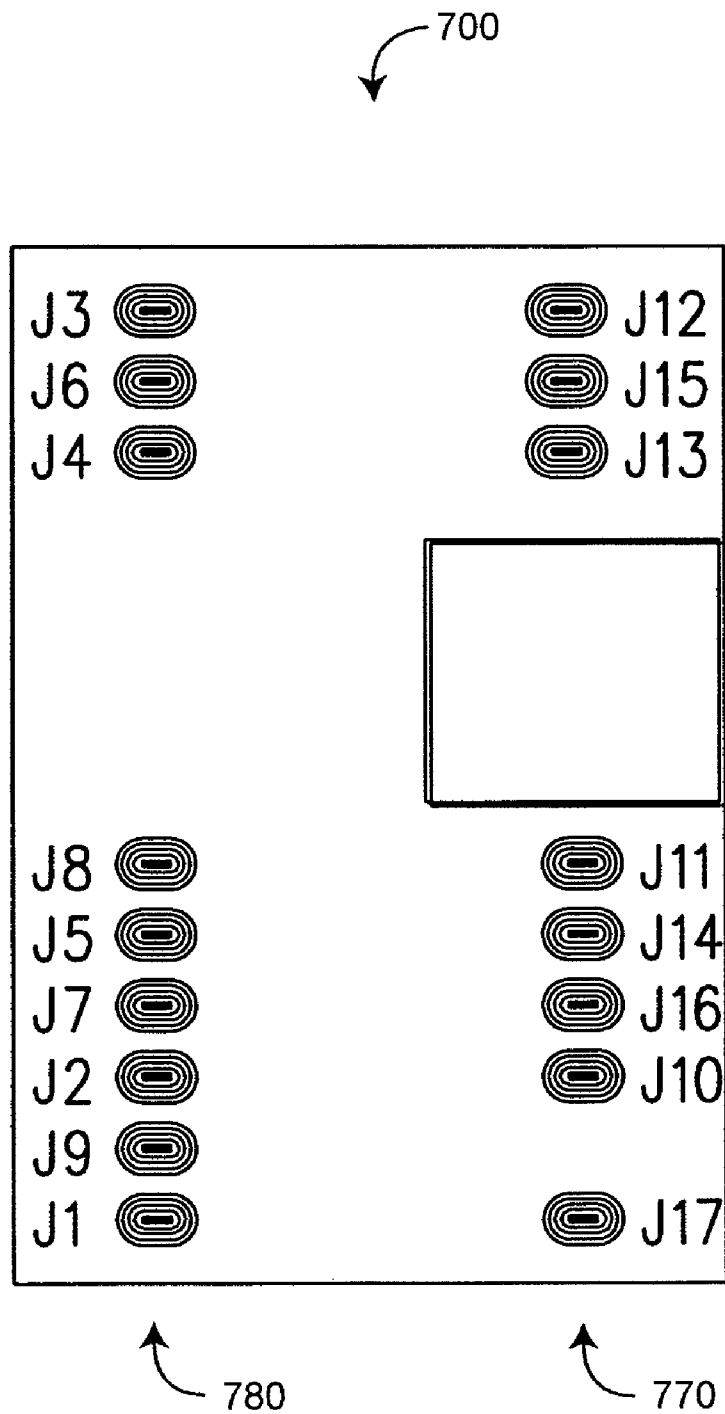


FIG. 7B

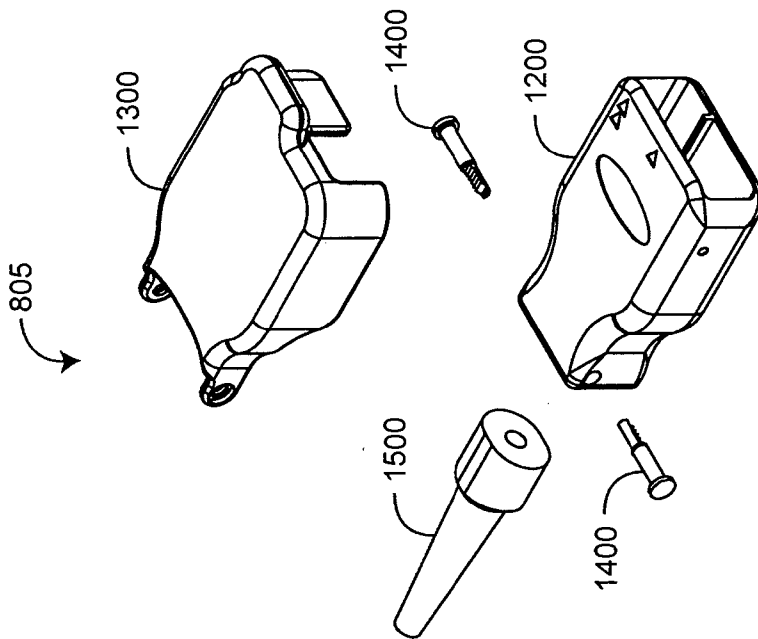


FIG. 8C

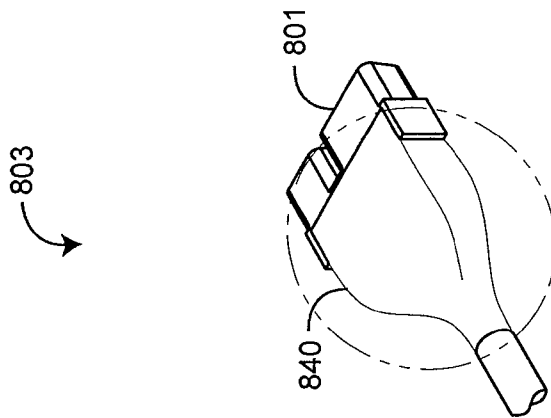


FIG. 8B

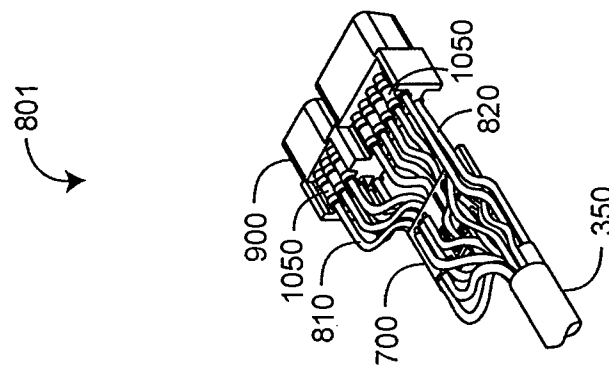


FIG. 8A

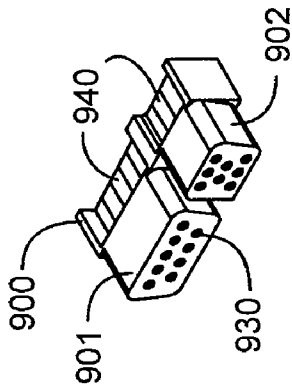


FIG. 9B

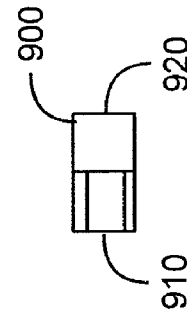


FIG. 9D

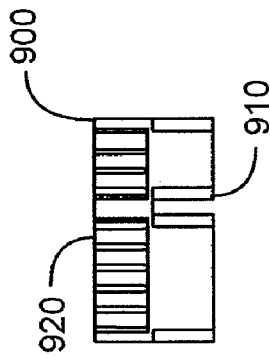


FIG. 9A

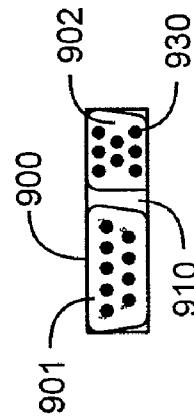


FIG. 9C

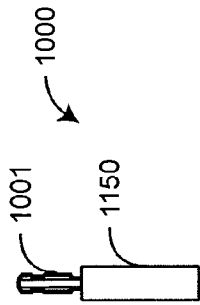


FIG. 10A

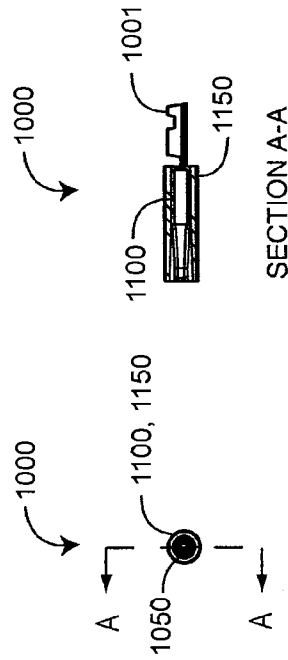


FIG. 10B

FIG. 10C

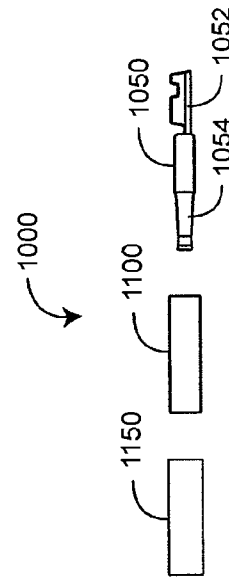


FIG. 10D

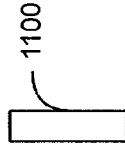


FIG. 11A

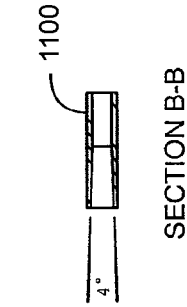


FIG. 11B

FIG. 11C

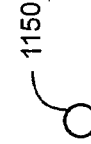
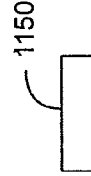


FIG. 11D

FIG. 11E



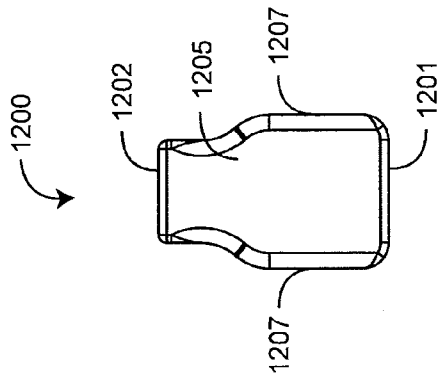


FIG. 12C

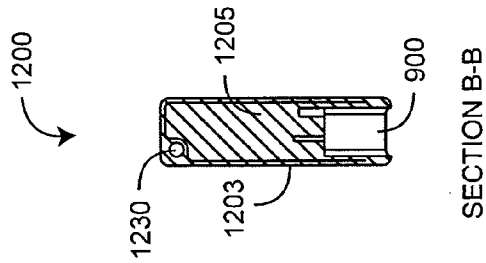


FIG. 12B

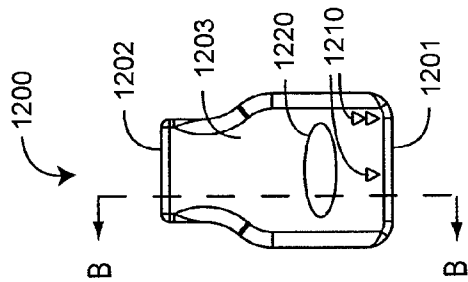


FIG. 12A

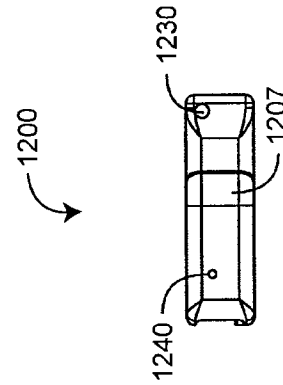


FIG. 12E

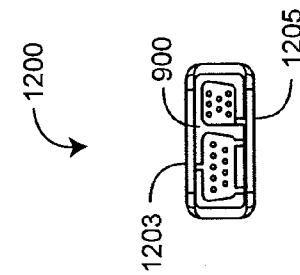


FIG. 12D

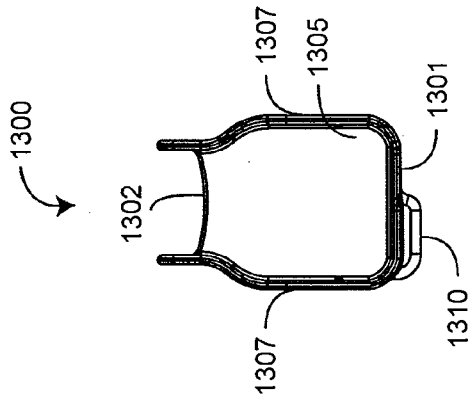


FIG. 13C

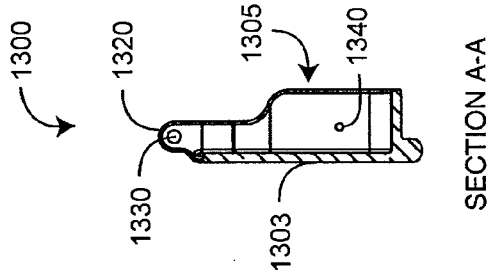


FIG. 13B

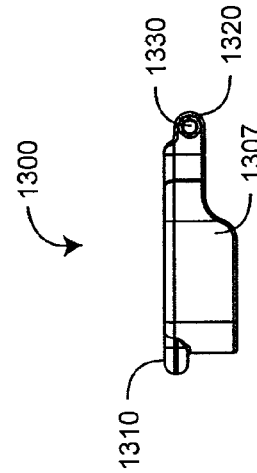


FIG. 13E

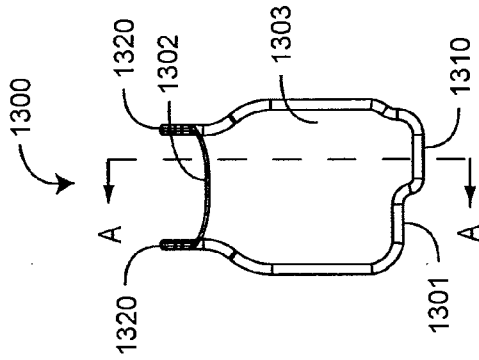


FIG. 13A

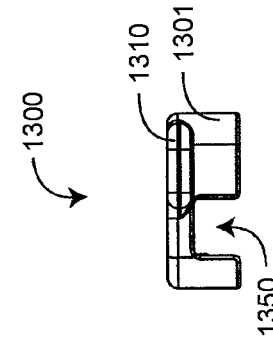


FIG. 13D

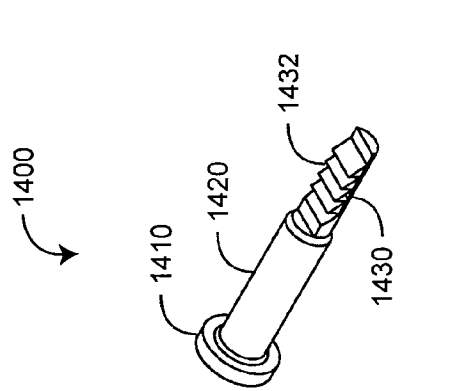


FIG. 14A

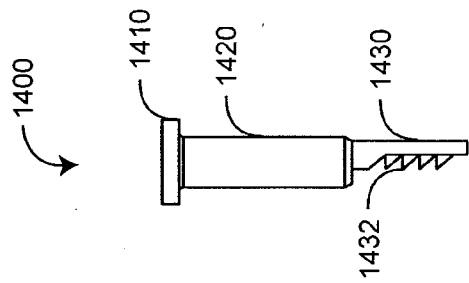


FIG. 14B

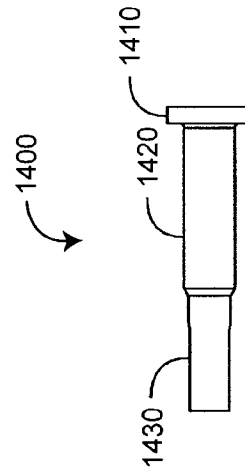


FIG. 14C

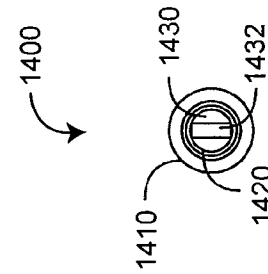


FIG. 14D

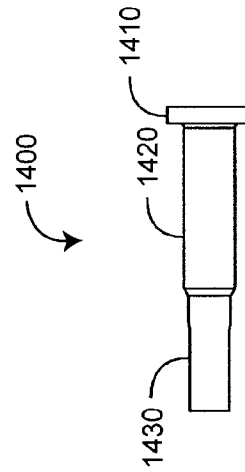


FIG. 14E

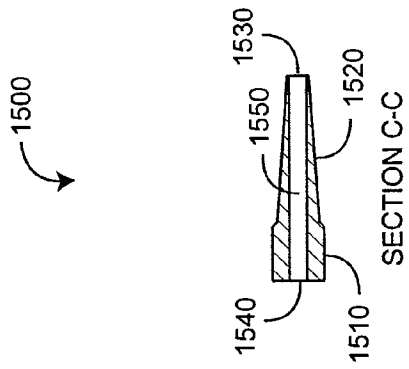


FIG. 15B

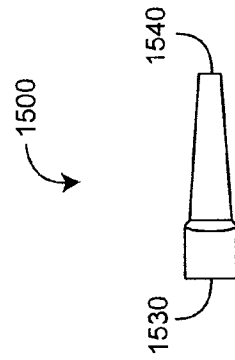


FIG. 15C

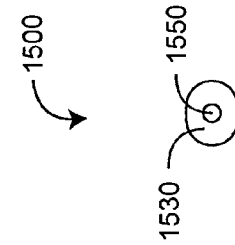
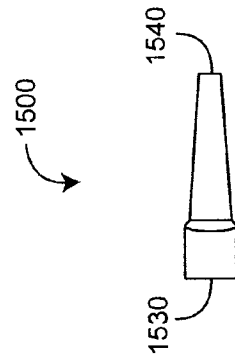


FIG. 15D



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DUO CONNECTOR PATIENT CABLE**REFERENCE TO RELATED APPLICATION**

[0001] The present application claims priority benefit under 35 U.S.C. §119(e) from U.S. Provisional Application No. 60/846,260, filed Sep. 20, 2006, entitled "Duo Connector Patient Cable," which is incorporated herein by reference.

BACKGROUND OF THE INVENTION

[0002] Pulse oximetry provides a noninvasive procedure for measuring the oxygen status of circulating blood and has gained rapid acceptance in a wide variety of medical applications, including surgical wards, intensive care and neonatal units, general wards, and home care and physical training. A pulse oximetry system has a physiological sensor applied to a patient, a monitor, and a patient cable connecting the sensor and the monitor. The sensor has light emitters and a detector, which are attached to a tissue site, such as a finger. The patient cable transmits emitter drive signals from the monitor to the sensor. The emitters respond to the drive signals so as to transmit light into the tissue site. The detector is responsive to the emitted light after attenuation by pulsatile blood flowing in the tissue site, generating a detector signal to the monitor. The monitor processes the detector signal to provide a numerical readout of physiological parameters such as oxygen saturation (SpO₂) and pulse rate.

[0003] FIG. 1 illustrates portions of a pulse oximetry system 100 having a monitor 110, a sensor 120 and a patient cable 130 interconnecting the monitor 110 and sensor 120. The sensor 120 has LEDs 121, 125 capable of emitting light having two wavelengths into a tissue site. The LEDs 121, 125 are configured in a back-to-back arrangement so that a first contact 132 is connected to a first LED cathode 122 and a second LED anode 127. A second contact 134 is connected to a first LED anode 123 and a second LED cathode 126. The monitor 110 has a first driver 112 and a second driver 114. The first contact 132 is in communications with a first driver 112 and the second contact 134 is in communications with a second driver 114. The first LED 121 is activated when the first driver 112 is pulled to Vcc and the second driver 114 provides a current sink to ground. The second LED 125 is activated when the second driver 114 is pulled to Vcc and the first driver 112 provides a current sink to ground. Pulse oximeters capable of reading through motion induced noise are available from Masimo Corporation ("Masimo") of Irvine, Calif. Pulse oximeters capable of reading through motion induced noise are also disclosed in at least U.S. Pat. Nos. 6,770,028, 6,658,276, 6,157,850, 6,002,952, 5,769,785, and 5,758,644, which are assigned to Masimo and are incorporated by reference herein.

SUMMARY OF THE INVENTION

[0004] A physiological measurement system can also be a multiple parameter monitor and a multiple wavelength sensor that provide enhanced measurement capabilities as compared with conventional pulse oximetry. The physiological measurement system allows the measurement of blood constituents and related parameters in addition to oxygen saturation and pulse rate, such as carboxyhemoglobin (HbCO) and methemoglobin (HbMet) to name a few.

[0005] FIG. 2 illustrates a multiple parameter system 200 having a multiple parameter monitor 210, a multiple wavelength sensor 220 and a patient cable 230 interconnecting the monitor 210 and sensor 220. The sensor 220 has an emitter array 262 having multiple LEDs 264 together capable of emitting light having multiple wavelengths into a tissue site. Anode drivers 232 and cathode drivers 234 are electrically connected to the LEDs 264 and activate LEDs by addressing at least one row 266 and at least one column 268 of an electrical grid. In an embodiment, the emitter array 262 has LEDs 264 connected within an electrical grid of n rows and m columns totaling n+m drive lines, where n and m integers greater than one. In an embodiment, the emitter array 262 comprises up to sixteen LEDs 264 configured in an electrical grid of four rows and four columns. Each of the four anode drive lines 272 provide a common anode connection to four LEDs 264, and each of the four cathode drive lines 274 provide a common cathode connection to four LEDs 264. Thus, the sixteen LEDs 264 are advantageously driven with only eight wires, including four anode drive lines 272 and four cathode 274 drive lines.

[0006] Also shown in FIG. 2, anode drivers 212 and cathode drivers 214 located in the monitor 210 selectively activate the LEDs 264. In particular, anode and cathode drivers function together as switches to Vcc and current sinks, respectively, to activate LEDs 264 and as switches to ground and Vcc, respectively, to deactivate LEDs. This push-pull drive configuration prevents parasitic current flow in deactivated LEDs. In a particular embodiment, only one anode drive line 232 is switched to Vcc at a time. One to four cathode drive lines 234, however, can be simultaneously switched to a current sink so as to simultaneously activate multiple LEDs within a particular row. Multiple parameter monitors and multiple wavelength sensors capable of measuring blood constituents such as carboxyhemoglobin (HbCO) and methemoglobin (HbMet) are available from Masimo. Further, multiple parameter monitors and multiple wavelength sensors are disclosed in at least U.S. patent application Ser. Nos. 11/367,033 and 11/367,013, which are assigned to Masimo Laboratories, Irvine, Calif. and are incorporated by reference herein.

[0007] A duo connector patient cable is advantageously configured to accommodate either of two types of mating sensor connectors including a conventional connector for a pulse oximetry sensor and a multiple wavelength sensor connector. Further, a duo connector patient cable advantageously converts drive signals for array configured emitters into drive signals for back-to-back configured emitters. In additional, a duo connector patient cable advantageously reconfigures connector pinouts for a multiple wavelength sensor to optimize signal-to-noise ratio (SNR) performance.

BRIEF DESCRIPTION OF THE DRAWINGS

[0008] FIG. 1 is a block diagram of a conventional pulse oximetry system;

[0009] FIG. 2 is a block diagram of a multiple parameter system;

[0010] FIG. 3A is a general block diagram of a duo connector patient cable utilized by a patient monitoring system;

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[0011] FIG. 3B is a top view of a duo connector patient cable embodiment that accommodates a conventional pulse oximetry sensor connector and a multiple wavelength sensor connector;

[0012] FIGS. 4A-F are perspective, top, front, side, retainer hinged-open front and retainer hinged-open side views of a duo connector, respectively;

[0013] FIGS. 5A-C are a front view of a duo connector, a front view of a monitor connector and a schematic of a duo connector patient cable, respectively;

[0014] FIG. 6 is a block diagram of a multiple parameter patient monitoring system utilizing a duo connector patient cable;

[0015] FIG. 7A is a block diagram of a duo connector patient cable circuit;

[0016] FIG. 7B is a top layout view of a duo connector circuit board;

[0017] FIGS. 8A-C are perspective views of duo connector assemblies;

[0018] FIGS. 9A-D are top, perspective, front and side views, respectively, of a duo connector socket;

[0019] FIGS. 10A-D are top, front, side cross sectional and side exploded views, respectively, of a detector socket pin;

[0020] FIGS. 11A-C are top, front and side cross sections views, respectively, of a detector socket pin shroud;

[0021] FIGS. 11D-E are front and side views, respectively, of a detector socket pin shield;

[0022] FIGS. 12A-E are top, side cross sectional, bottom, front and side views, respectively, of a duo connector shell overmolded on a socket;

[0023] FIGS. 13A-E are top, side cross sectional, bottom, front and bottom views, respectively, of a duo connector retainer;

[0024] FIGS. 14A-E are top, side, perspective, front and side views, respectively, of a duo connector hinge pin; and

[0025] FIGS. 15A-D are top, side cross sectional, front and side views, respectively, of a duo connector strain relief.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0026] FIG. 3A generally illustrates a duo connector patient cable 300 as part of a patient monitoring system. Advantageously, the duo connector patient cable 300 allows both a SpO₂ sensor 10 and a multiple wavelength sensor 20 to communicate with a multiple parameter monitor 50. In particular, a duo connector 310 accepts both a conventional pulse oximetry sensor and a multiple wavelength sensor, each having different connectors 12, 22. In an embodiment, the duo connector accepts a WTM LNCS® low noise enabled sensor and a RAINBOW™ multiple wavelength sensor. LNCS® brand sensors and RAINBOW™ brand monitors and sensors are available from Masimo Corporation. In addition, the duo connector patient cable 300 has an adapter circuit 600 that converts array drive signals configured for a multiple wavelength sensor 20 so as to drive back-to-back emitters of a SpO₂ sensor 10. Further, the

adapter circuit 600 reconfigures the duo connector patient cable 300 to a signal and ground pinout that has improved signal-to-noise ratio (SNR) and crosstalk performance when connected to a multiple wavelength sensor. An adapter circuit 600 is described in further detail with respect to FIGS. 6-7, below.

[0027] FIG. 3B illustrates a duo connector patient cable 300 having a duo connector 400, a monitor connector 310 and a cable 350 having wires that interconnect the duo connector 400 and monitor connector 310. The duo connector 400 advantageously accommodates a conventional SpO₂ sensor connector 15 and a multiple wavelength sensor connector 1800. In an embodiment, a SpO₂ sensor 10 is plugged into the patient cable 300 so that a SpO₂ sensor alignment arrow 16 matches a first patient cable alignment arrow 401. Also a multiple wavelength sensor 20 is plugged into the patient cable 300 so that a multiple wavelength sensor alignment arrow 1803 matches a second patient cable alignment arrow 402. The cable alignment arrows 401, 402 (shown hidden) are inscribed on a connector shell 1200 (FIG. 12A) covered by a retainer 1300 (FIGS. 13A-E) that is opened during sensor attachment. In an embodiment, the SpO₂ sensor connector 15 is a 9-pin mini-D connector, which is well-known in the art. The monitor connector 310 is a 20-pin DB connector, which is also well-known in the art and further described with respect to FIG. 5B, below. Physical aspects of the duo connector 400 are described generally with respect to FIGS. 4A-F and in greater detail with respect to FIGS. 8-15. The duo connector signals, grounds and pinouts are described with respect to FIGS. 5-7. The adapter circuit 600 (FIG. 6) for configuring the duo connector 400 to accommodate either a two-wavelength SpO₂ sensor or a multiple wavelength sensor is described with respect to FIGS. 6-7.

[0028] FIGS. 4A-F illustrate a duo connector 400 having a front 401 and a back 402. The front 401 has a socket 900 that accommodates either of two mating sensor plugs 15, 1800 (FIG. 3B). The back 402 terminates a cable 350 (FIG. 3B). The duo connector socket 900 has a first socket section 901 configured for a conventional SpO₂ sensor plug 15 (FIG. 3B) and a second socket section 902, which along with the first socket section 901 is configured for a multiple wavelength sensor plug 1800 (FIG. 3B). In particular, the first socket section 901 has pinouts for back-to-back LED drive signals from a monitor to a sensor and detector signals and sensor information from the sensor to the monitor. The second socket section 902 has pinouts for LED array drive signals from a monitor to a sensor. The pinouts for the socket sections 901, 902 are described in further detail with respect to FIGS. 5A-C, below. The duo connector 400 also has a retainer 1300 movable between a closed position (FIGS. 4A-D) and an open position (FIGS. 4E-F). In the open position, the retainer 1300 allows either sensor plug 15, 1800 (FIG. 3B) to be inserted into or removed from the socket 900. In the closed position, the retainer 1300 prevents either sensor plug 15, 1800 (FIG. 3B) from inadvertently disconnecting from the socket 900.

[0029] FIGS. 5A-C illustrate a duo connector patient cable 300. In particular, the socket 900 (FIG. 5A) and the corresponding sensor pinouts 520 (FIG. 5C) relate to the duo connector 400 (FIG. 5A). Also, the monitor socket 312 (FIG. 5B) and the corresponding monitor pinouts 510 relate to the monitor connector 310 (FIG. 5B). Also illustrated in is a

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circuit board 700 (FIG. 5C) that resides in the duo connector 400, as described with respect to FIGS. 7-8, below, and that switches the pinouts under monitor control according to the sensor 10, 20 (FIGS. 3A-B) plugged into the duo connector 400.

[0030] As shown in FIGS. 5A-C, the duo connector pinouts 520 are divided into pins 1-9, associated with a first socket section 901 and pins 10-17 associated with a second socket section 902. When a SpO₂ sensor 10 (FIGS. 3A-B) is inserted into the first socket section 901, the monitor detects the SpO₂ sensor from the “1-wire comm” line connecting the sensor side (pin 4) 520 and the monitor side (pin 15) 510. The monitor then sets the “control” line on pin 8510 so that the circuit board 700 converts the first two LED cathode drive signals (pins 3, 13) 510 and LED anode drive signals (pins 1, 11) 510 to a red cathode drive signal (pin 2) 520 and an IR cathode drive signals (pin 3) 520.

[0031] Also as shown in FIGS. 5A-C, when a multiple wavelength sensor 20 (FIGS. 3A-B) is inserted into the socket sections 901, 902, the monitor detects the sensor from the “1-wire comm” line connecting the sensor side (pin 4) 520 and the monitor side (pin 15) 510. The monitor then sets the “control” line (pin 8) 510 so that the circuit board 700 grounds the now unused drive signal lines (pins 2, 3) 520. That is, for the higher performance multiple wavelength sensor 20 (FIGS. 3A-B), the detector signals (pins 5, 9) 520 on the first socket section 901 are advantageously isolated from the drive signals (pins 10-17) 520 on the second socket section 902. This reduces the possibility of cross-talk from drive lines to detector lines. Further, the detector signals (pins 5, 9) 522 are separately shielded 1150, and the shields 1150 are grounded to a cable inner shield (pin 6) 524, providing further noise immunity for the detector signal.

[0032] FIG. 6 illustrates portions of a multiple parameter system embodiment having a multiple parameter monitor 50 and a duo connector patient cable 300 interconnecting either a SpO₂ sensor 10 or a multiple wavelength sensor 20. The duo connector patient cable 300 advantageously incorporates an adapter circuit 600 allowing the multiple parameter monitor 50 to drive either back-to-back (red and IR wavelength) LEDs 12 of a SpO₂ sensor 10 or a LED array 22 of a multiple wavelength sensor 20. In particular, the patient cable 300 has array lines 610 configured to communicate array drive signals 52 to a LED array 22, as described with respect to FIG. 2, above. The patient cable 300 also has an adapter circuit 600 that configures an array line subset 612 so as to communicate array drive signals 52 to back-to-back LEDs 12.

[0033] As shown in FIG. 6, the adapter circuit 600 incorporates switches 660 that selectively route the array line subset 612 so that the array drive signals 52 activate the back-to-back LEDs 12 when the monitor 50 senses a SpO₂ sensor 10 is connected to the patient cable 300. When the monitor 50 senses a multiple wavelength sensor 20 is connected to the patient cable 300, the switches 660 advantageously ground certain of the sensor connector pins (not shown) so as to minimize cross-talk between drive signals 52 and detector signals (not shown), as described in further detail below. In an embodiment, the monitor 50 utilizes eight array lines 610 to drive a four-by-four emitter array 22 of up to sixteen LEDs. Four of the array lines 612 are routed

through the switches 660 to back-to-back lines 614, as described in further detail with respect to FIGS. 7A-B, below.

[0034] Also shown in FIG. 6, in an embodiment, a network controller 56 monitors a network 630 so as to read an information element from either sensor 10, 20 to identify either a SpO₂ sensor 10 or a multiple wavelength sensor 20. The network controller 56 can also read the EEPROM 670 over the network 630 so that the monitor 50 can identify a duo sensor patient cable 300 is attached. The monitor 50 also has a switch control 54 that provides a control 620 in response to information from the network 630. That is, the control 620 configures the switches 660 according to the sensor 10, 20 that is attached to the duo connector patient cable 300.

[0035] FIGS. 7A-B illustrate an adapter circuit 600 and a corresponding circuit board 700. As shown in FIG. 7A, an adapter circuit 600 embodiment has array lines 612, a control 620 and a network 630, as described with respect to FIG. 6, above. The adapter circuit 600 also has switch 660 and an EEPROM 670, as described with respect to FIG. 6, above. The array lines 612, control 620 and network 630 connect to a monitor 50 (FIG. 6) via monitor-side pads 780. The array lines 612 and network 630 also connect to a sensor 10, 20 (FIG. 6) via sensor-side pads 770. Switches 660 include a first switch IC 662 and a second switch IC 664 each having dual single-pole, double-throw switches responsive to the control 620. In an embodiment, the switch ICs 662, 664 are each MAX 4684 available from Maxim Integrated Products, Inc., Sunnyvale, Calif. (“Maxim”). In an embodiment, the network 630 is a single wire, and the EEPROM is a DS2431X, also available from Maxim. As shown in FIG. 7B the circuit board 700 has a plurality of solder pads 770, 780 adapted for wire connections. Sensor-side pads 770 accommodate jumper wires 810 (FIG. 8A) to duo connector pins. Monitor-side pads 780 accommodate wires from the cable 350 (FIG. 3).

[0036] Also shown in FIG. 7A, when the control 620 is asserted, the four switches route a combination of cathode1 and anode1 signal and a combination of cathode2 and anode2 signal to the IR and red cathodes 614, respectively. In this manner, the monitor can activate the back-to-back LEDs as if connected in an array. That is, an IR LED is activated by pulling up cathode1 and current sinking anode2 and a red LED is activated by pulling up cathode 2 and current sinking anode1. When the control 620 is not asserted, the first switch IC 662 grounds the IR and red cathode lines 614. In this manner, when a SpO₂ sensor is not connected, the drive lines proximate to the detector lines are grounded, so as to reduce the possibility of signal crosstalk inducing noise on the detector signal, as described above.

[0037] FIGS. 8A-C illustrate duo connector assemblies including a wiring assembly 801, a shielded wiring assembly 803 and a shell assembly 805. As shown in FIG. 8A, the wiring assembly 801 includes a circuit board 700, a socket 900, a cable 350, jumper wires 810, cable wires 820 and socket pins 1050. A first portion of the cable wires 820, including detector wires and a first portion of array drive wires, extend to the socket pins 1050. A second portion of the cable wires 820, including a network wire, a control wire, and a second portion of the array drive wires, extend to monitor-side pads 780 (FIG. 7B) of the circuit board 700.

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The jumper wires **810** extend between the sensor-side pads **770** (FIG. 7B) of the circuit board **700** and the socket pins **1050** and include the red and IR cathode drive wires and the network wire. The socket **900** is described in detail with respect to FIGS. 9A-D, below. The socket pins **1050** are described with respect to FIGS. 10-11, below.

[0038] As shown in FIG. 8B, the shielded wiring assembly **803** has a socket overmold **840** sealing the wiring assembly **801** so that no wires are exposed. The overmold is covered with a copper shield, which is grounded to the cable outer shield **526** (FIG. 5C). In an embodiment, the socket overmold **820** is a PVC material.

[0039] As shown in FIG. 8C, the shielded wiring assembly **803** is housed in the shell assembly **805**. The shell assembly **805** has a shell **1200**, a retainer **1300**, hinge pins **1400** and a bend relief **1500**. The shell **1200** encloses the shielded wiring assembly **803**. The retainer **1300** is hinged to the shell **1200** so as to removably retain either of the sensor connectors **15, 1800** (FIG. 3). The hinge pins **1400** secure the retainer **1300** to the shell **1200**. The bend relief **1500** protects the cable and cable wires proximate the shell **1200**. In an embodiment, the shell **1200** and the bend relief **1500** are overmolded to the shielded wiring assembly **803**. In a particular embodiment, the shell and bend relief overmolds are cast at the same time so that the bend relief **1500** is fused to the shell **1200**. The shell **1200** is described in further detail with respect to FIGS. 12A-E, below. The retainer **1300** is described in further detail with respect to FIGS. 13A-E, below. The hinge pins **1400** are described in further detail with respect to FIGS. 14A-E. The bend relief **1500** is described in further detail with respect to FIGS. 15A-D, below.

[0040] FIGS. 9A-D illustrate a socket **900** having a front **910**, a back **920**, socket sections **901, 902** proximate the front **910**, socket apertures **930** arranged in rows and extending through the socket sections **901, 902** and pin holders **940** proximate the back **920** also arranged in rows corresponding to the socket apertures **930**. Each socket aperture **930** accepts a socket pin **1050** (FIG. 10D), which mates with corresponding plug pins extending from a sensor plug **15, 1800** (FIG. 3B). Wiring of the socket **900** and socket pins **1050** (FIG. 10D) are described above with respect to the wiring assembly **801** (FIG. 8B). Socket pins including shielded detector sockets **1000** (FIGS. 10A) are described in detail with respect to FIGS. 10-11, below.

[0041] FIGS. 10A-D illustrate a socket pin **1050** and a shielded detector socket **1000** utilizing the socket pin **1050**. The socket pin **1050** has a crimp **1052** for attaching wires and a body **1054** for receiving a mating connector pin. In an embodiment, the socket pin **1050** is a phosphor bronze with gold over nickel plating. A detector socket **1000** has a socket pin **1050**, an insulating shroud **1100** and a shield **1150**. The two detector lines **522** (FIG. 5C) are terminated at two corresponding detector sockets **1000**, with the shield **1150** extending from the socket apertures **930** (FIGS. 9B-C) proximate the pin holders **940** (FIG. 9B) and connected to the cable inner shield **524** (FIG. 5C).

[0042] FIGS. 11A-C illustrate the detector socket shroud **1100** and shield **1150**. The shroud **1100** accepts a socket pin body **1054** (FIG. 10D) and fits within the shield **1150**. In an embodiment, the shroud **1100** is polypropylene or DuPont Delrin®, and the shield is copper.

[0043] FIGS. 12A-E illustrate a duo connector shell **1200** that houses a shielded wiring assembly **803** (FIG. 8B) including a socket **900**. The shell **1200** is a generally rectangular enclosure having a front **1201**, a back **1202**, a top **1203** and a bottom **1205**. The shell **1200** is tapered proximate the back **1202** which is narrower than the front **1201**. On the top **1203**, the shell **1200** has arrow indicators **1210** proximate the front **1201** and an artwork recess **1220**. On both sides **1207**, the shell **1200** has hinge apertures **1230** and depressions **1240**. The front **1201** accommodates the socket sections **900** which accepts corresponding sensor connectors **15, 1800** (FIG. 3B). The back **1202** accommodates a patient cable **350** (FIG. 3B) which is supported to proximate the shell **1200** by a bend relief **1500** (FIGS. 15A-D). The arrow indicators **1210** match with corresponding sensor connector indicators **16, 1803** (FIG. 3B) providing a sensor connector alignment guide, as described with respect to FIG. 3B, above. The hinge apertures **1230** accommodate the hinge pins **1400** (FIGS. 14A-E) that attach the retainer **1300** (FIGS. 13A-E) to the shell **1200**, as described with respect to FIGS. 4A-F, above. The depressions **1240** accept corresponding retainer protrusions **1340** (FIG. 13B) so as to releasably hold the retainer **1300** in a closed position shown in FIGS. 4A-D. In an embodiment, the shell **1200** is overmolded on the shielded wiring assembly **803** (FIG. 8B), including the socket **900**. In an embodiment, the shell **1200** is medical grade PVC of 90-100 Shore A durometer.

[0044] FIGS. 13A-E illustrate a duo connector retainer **1300** configured to hinge to the shell **1200** (FIGS. 12A-E) so as to removably retain sensor connectors **15, 1800** (FIG. 3B). The retainer **1300** is a generally rectangular cover having a front **1301**, a back **1302**, a top **1303** and a bottom **1305** and is configured to fit at least partially over the shell front **1201**, top **1203** and sides **1207** (FIGS. 12A-E). Proximate the front and top **1301, 1303**, the retainer **1300** has a protruding tab **1310** that accommodates a person's finger or thumb to easily open or close the retainer. Protruding from the retainer back **1302** and proximate the retainer sides **1307** are hinges **1320**, each having a hinge aperture **1330** configured to match up with corresponding shell hinge apertures **1230** (FIG. 12E) so as to accommodate hinge pins **1400** (FIGS. 14A-E). Extending inwardly from the retainer sides **1307** are protrusions **1340** (FIG. 13B) configured to click into corresponding shell depressions **1240** (FIG. 12E) so as to releasably hold the retainer **1300** in a closed position (FIGS. 4A-D). The front **1301** has a cable aperture **1350** offset from the tab **1310** and configured to accommodate sensor cables immediately behind the sensor connectors **15, 1800** (FIG. 3B) to prevent inadvertent disconnection of sensors **10, 20** (FIGS. 3A-B) from the duo connector **400** (FIG. 3B). In an embodiment, the retainer **1300** is a medical grade clear plastic.

[0045] FIGS. 14A-E illustrate a duo connector hinge pin **1400** that rotatably attaches the retainer **1300** (FIGS. 13A-E) to the shell **1200** (FIGS. 12A-E). In particular, a pair of pins **1400** insert through retainer apertures **1220** (FIGS. 12A-E) and shell apertures **1230** (FIGS. 13A-E) from opposite directions and are fixedly latched together. The pin **1400** has a generally round head **1410**, a cylindrical shaft **1420** extending generally normal to the head **1410**, and a partially cylindrical latching portion **1430** extending from the end of the shaft **1420** distal the head **1410**. A plurality of teeth **1432** are disposed on the latching portion **1430**. The teeth **1432** are configured to slide past corresponding teeth on an opposite

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pin **1400** in one direction only, so as to latch together opposite facing pins. So disposed, the pin heads **1410** hold the shell **1200** (FIGS. **12A-E**) relative to the retainer **1300** (FIGS. **13A-E**) as the retainer rotates about the pin shafts **1420**.

[0046] FIGS. **15A-D** illustrate a bend relief **1500** that protects the cable from bending forces and the cable wires and corresponding solder joints from pulling forces. The bend relief **1500** is a generally tapered cylinder having a head **1510**, a tail **1520**, a front **1530**, a back **1540** and an axial cavity **1550** extending the length of the bend relief. In an embodiment, the bend relief **1500** is overmolded on the patient cable **350** (FIG. **3B**) so that the cable **350** is retained within the axial cavity **1550** so formed. The head **1510** is disposed proximate the shell back **1202** (FIGS. **12A-E**), with the tail **1520** extending distal the shell **1200** (FIGS. **12A-E**). In an embodiment, the bend relief **1500** is medical grade PVC having a 40-50 Shore A durometer. In an embodiment, the bend relief **1500** and shell **1200** are overmolded at the same time so that the bend relief front **1530** fuses to the shell back **1202** (FIGS. **12A-E**).

[0047] A duo connector patient cable has been disclosed in detail in connection with various embodiments. These embodiments are disclosed by way of examples only and are not to limit the scope of the claims that follow. One of ordinary skill in art will appreciate many variations and modifications.

What is claimed is:

1. In a patient monitoring system having a sensor configured to transmit at least two wavelengths of optical radiation into a tissue site and detect the radiation after attenuation by pulsatile blood flowing within the tissue site, a patient monitor configured to process a signal responsive to the detected radiation and generate at least one parameter indicative of a patient physical condition, a patient cable for interconnecting the sensor and patient monitor comprising:

- a monitor connector configured to mate with a corresponding connector in a patient monitor;
- a sensor connector configured to mate with either of two types of sensor connectors; and
- a cable interconnecting the monitor connector and the sensor connector so as to transmit drive signals originating from the monitor to the sensor and to transmit sensor signals originating from the sensor to the monitor.

2. The patient cable according to claim 1 further comprising:

- a first socket section configured to mate with a two-wavelength pulse oximeter sensor; and
- a second socket section configured, along with the first socket section, to mate with a multiple wavelength sensor capable of transmitting more than two wavelengths of optical radiation into a tissue site.

3. The patient cable according to claim 2 further comprising a circuit for converting multiple wavelength sensor drive signals into two-wavelength sensor drive signals.

4. The patient cable according to claim 3 wherein the circuit comprises:

- a circuit board housed in the sensor connector; and

a plurality of switches mounted to the circuit board,

wherein the switches route portions of array drive signals generated by the monitor to back-to-back drive signal pins in communications with the two-wavelength sensor.

5. The patient cable according to claim 4:

wherein the back-to-back signal drive pins are housed in the first socket section, and

wherein the array drive signals for the multiple wavelength sensor are communicated to the second section;

6. The patient cable according to claim 5 further comprising:

detector signal pins housed in the first socket section in communications with either the two-wavelength sensor or the multiple wavelength sensor when attached,

wherein drive signal pins housed in the first section are grounded when the multiple wavelength sensor is attached so as to improve noise isolation of the detector signal.

7. A patient cable method comprising the steps of:

providing a duo sensor connector having a first socket section and a second socket section;

removably attaching a first sensor having a conventional connector to the first socket section for making pulse oximetry measurements; and

removably attaching a second sensor having a mating duo connector to the first and second socket sections for making blood parameter measurements in addition to pulse oximetry measurements.

8. The patient cable method according to claim 7 comprising the further steps of:

communicating first drive signals to the first socket section; and

communicating second drive signals to the second socket section,

wherein a portion of the second drive signals are routed to the first socket section as the first drive signals when the first sensor is attached to the duo sensor connector.

9. The patient cable method according to claim 8 comprising the further step of converting second drive signals from a multiple parameter patient monitor configured for an LED array to first drive signals configured for back-to-back LEDs when the first sensor is attached to the duo sensor connector.

10. The patient cable method according to claim 9 comprising the further step of switching signals between pins in the first socket section and the second socket section within the duo sensor connector.

11. The patient cable method according to claim 10 comprising the further step of grounding drive signal pins in the first socket section when the second sensor is attached to the duo sensor connector so as to provide noise isolation of detector signal pins in the first socket section.

12. A patient cable for connecting a patient monitor to an optical sensor comprising:

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a duo connector means for establishing communications between a monitor and one of a two-wavelength sensor having a conventional connector and a multiple wavelength sensor connector; and

an information means for identifying which of the sensors is attached to the duo connector means.

13. The patient cable according to claim 12 further comprising:

a switching means for converting array drive signals from the monitor to back-to-back drive signals for the two-wavelength sensor; and

a housing means for mounting the switching means with the duo connector means.

14. The patient cable according to claim 13 further comprising a configuration means for achieving improved noise isolation for a sensor signal when the multiple wavelength is attached to the duo connector means.

15. The patient cable according to claim 14 further comprising an overmold means for housing the duo connector means and the switching means and for creating a bend relief means.

* * * * *

EXHIBIT 12



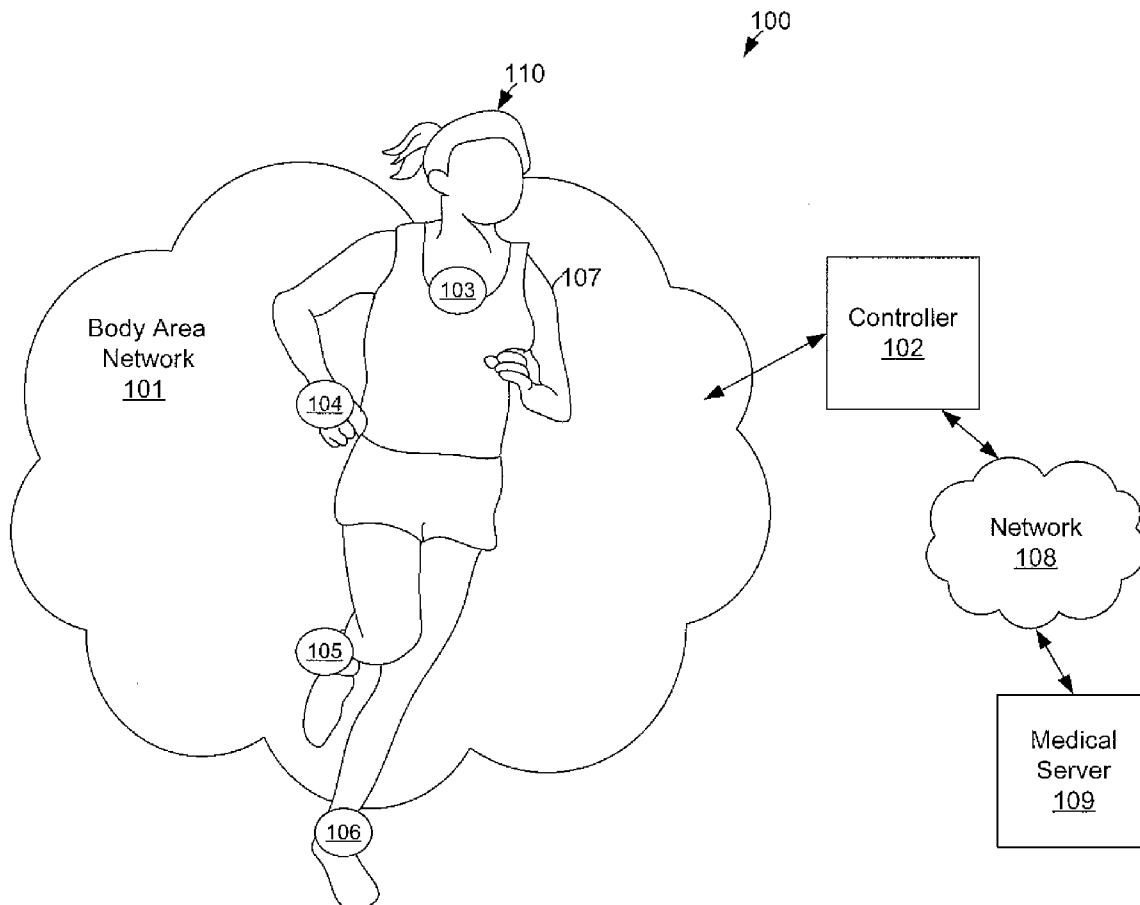
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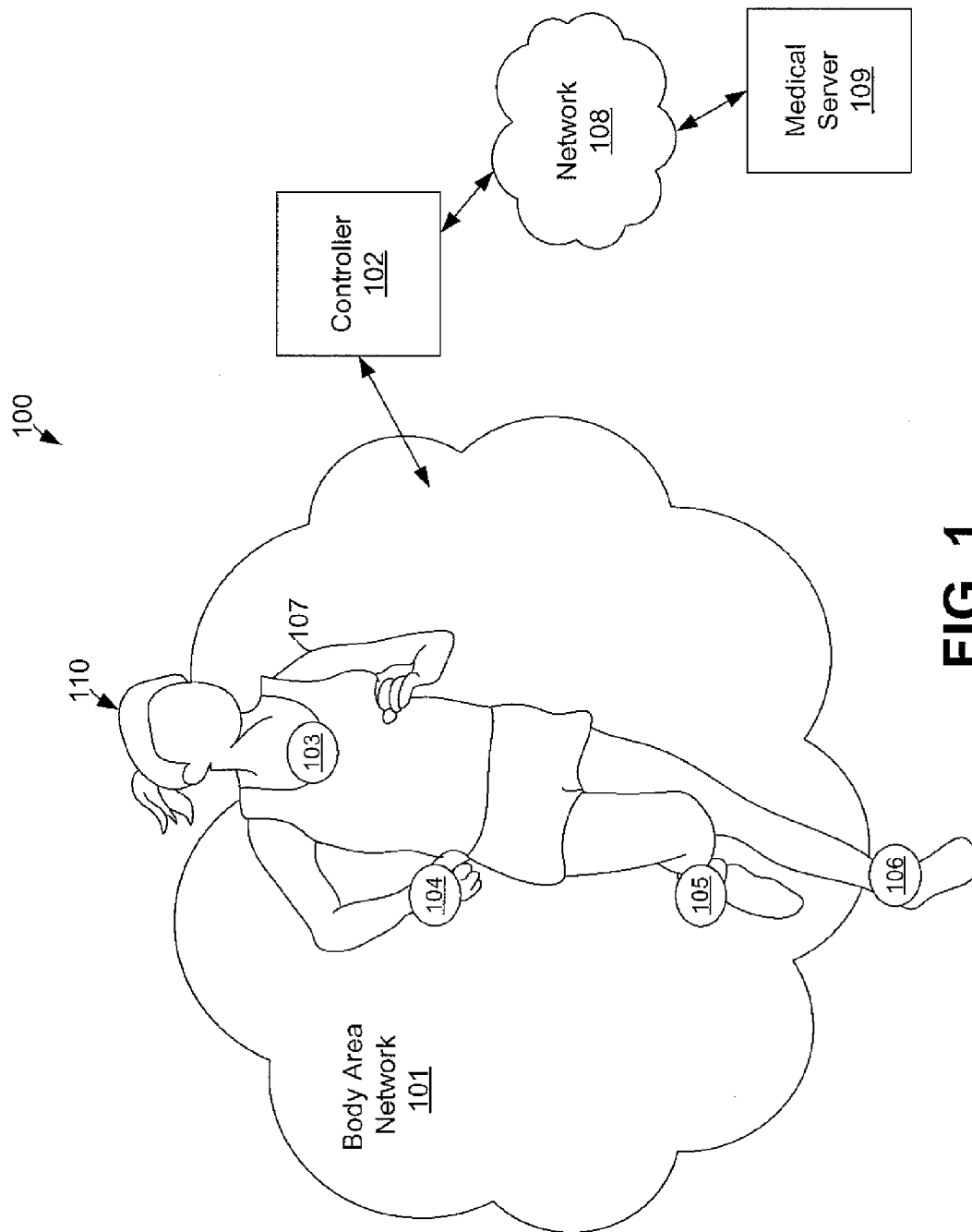
(19) **United States**(12) **Patent Application Publication**
Otto(10) **Pub. No.: US 2008/0211657 A1**(43) **Pub. Date: Sep. 4, 2008**(54) **WIRELESS SENSOR NETWORK
CALIBRATION SYSTEM AND METHOD**(22) Filed: **Jan. 10, 2008****Related U.S. Application Data**(75) Inventor: **Chris A. Otto, Huntsville, AL (US)**

(60) Provisional application No. 60/884,352, filed on Jan. 10, 2007.

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HUNTSVILLE, AL 35804-2087 (US)(51) **Int. Cl.**
G08B 1/00 (2006.01)(52) **U.S. Cl.** **340/501**(57) **ABSTRACT**(73) Assignee: **Halo Monitoring, Inc., Huntsville, AL (US)**

A system has at least one sensor and a controller communicatively coupled to the sensor. The system further has logic configured to calculate a calibration value based upon an initial state of the sensor and store the calibration value in memory.

(21) Appl. No.: **11/972,197**



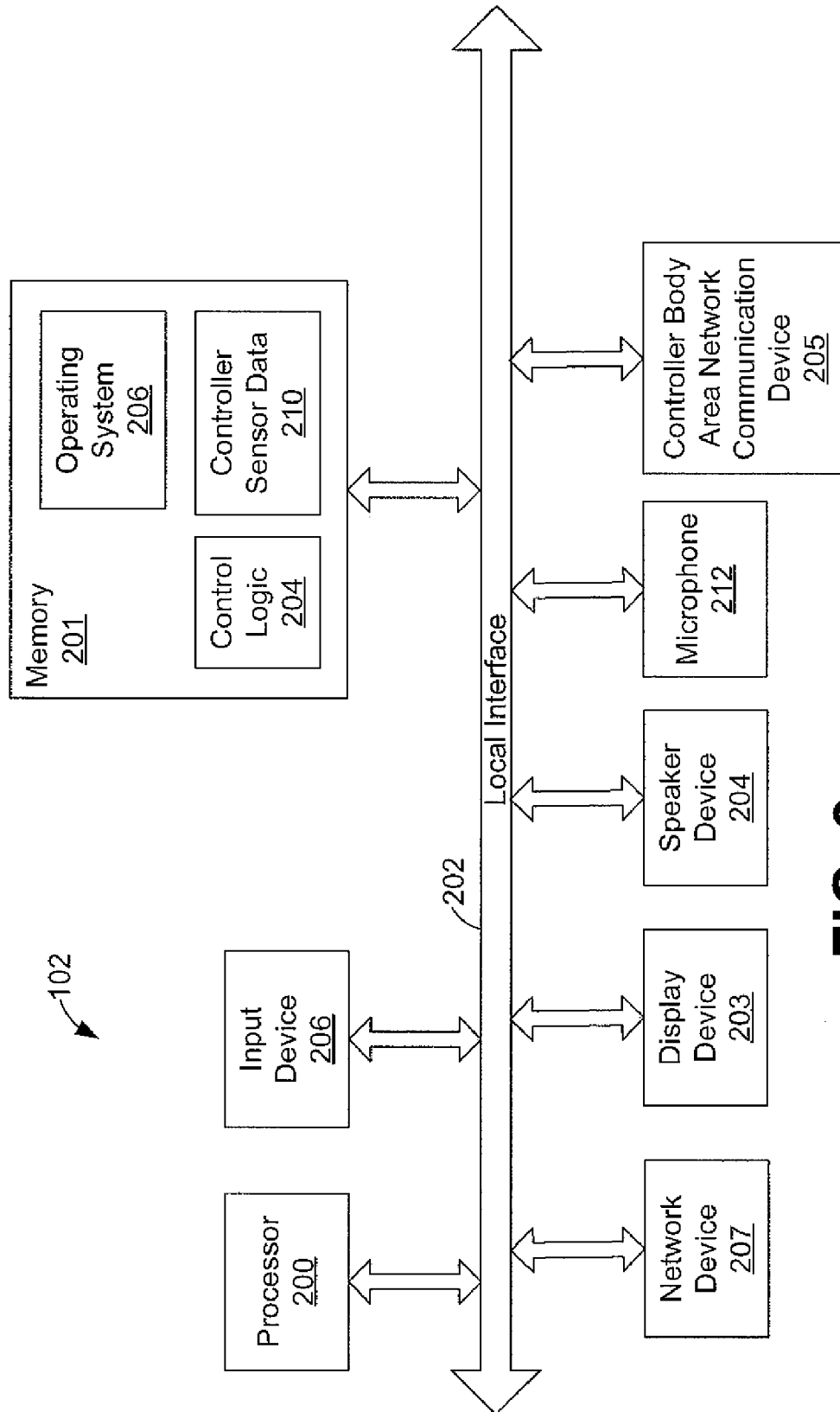


FIG. 2

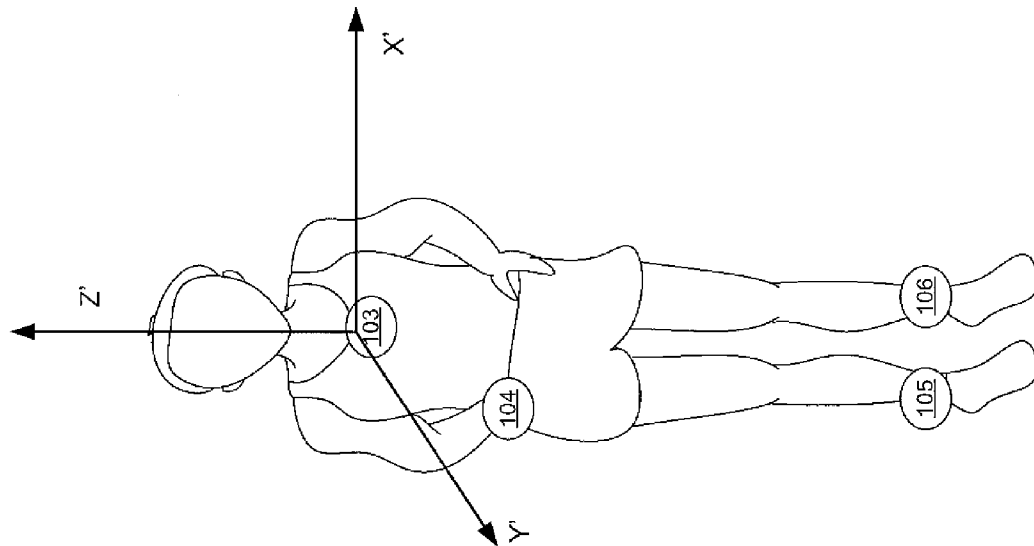


FIG. 3

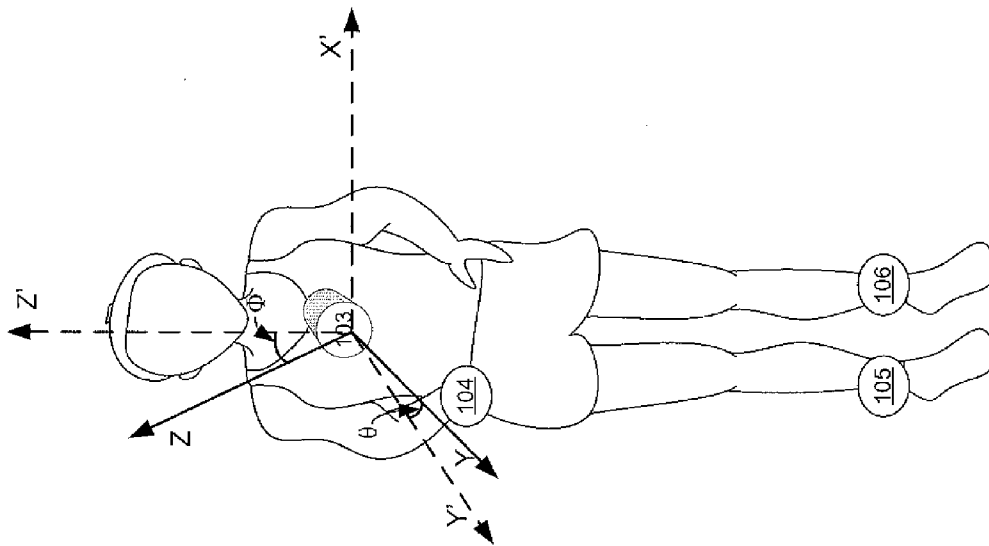


FIG. 4

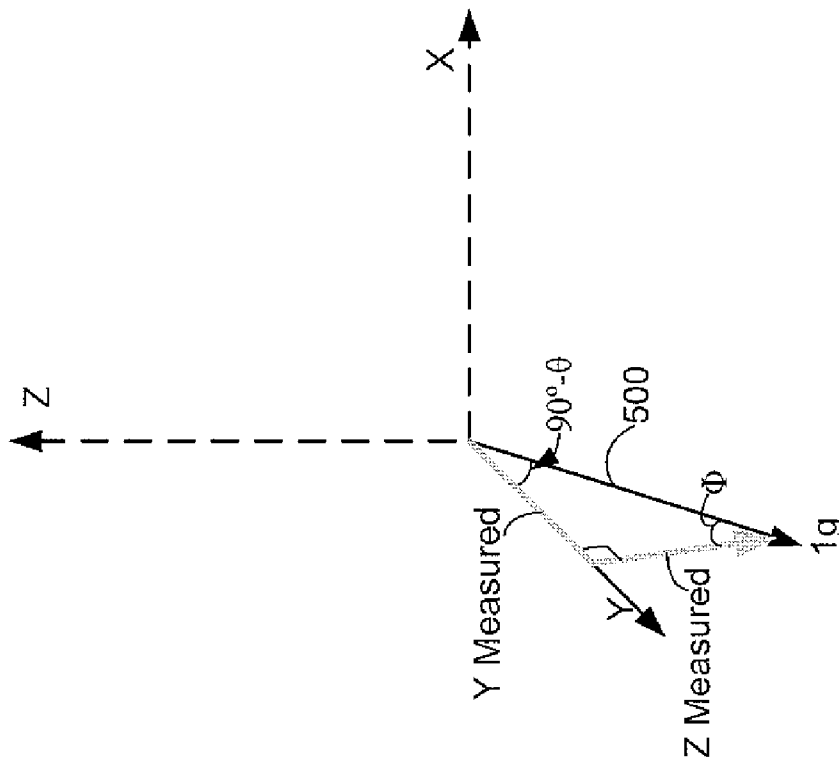


FIG. 6

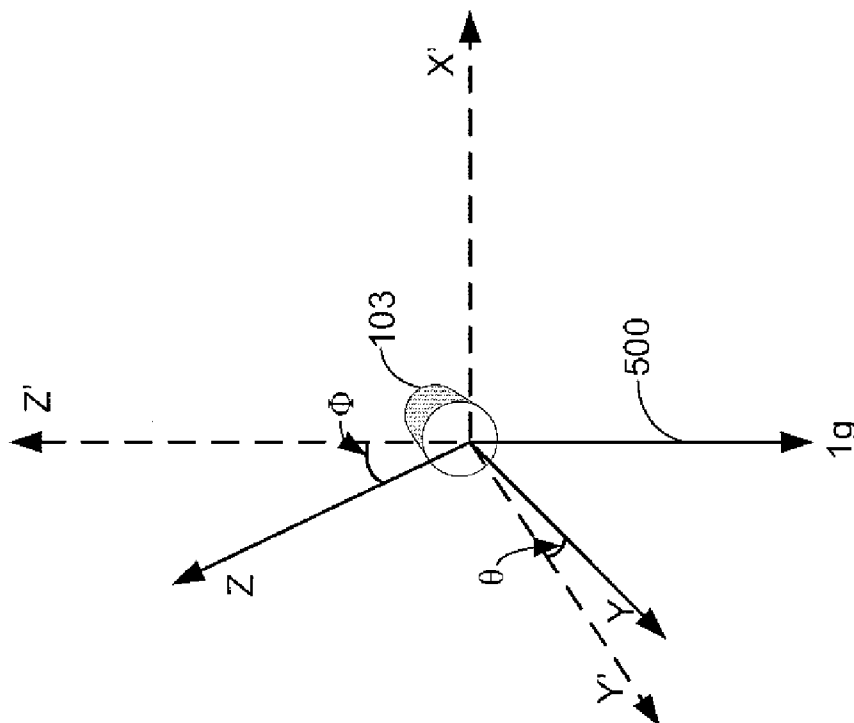
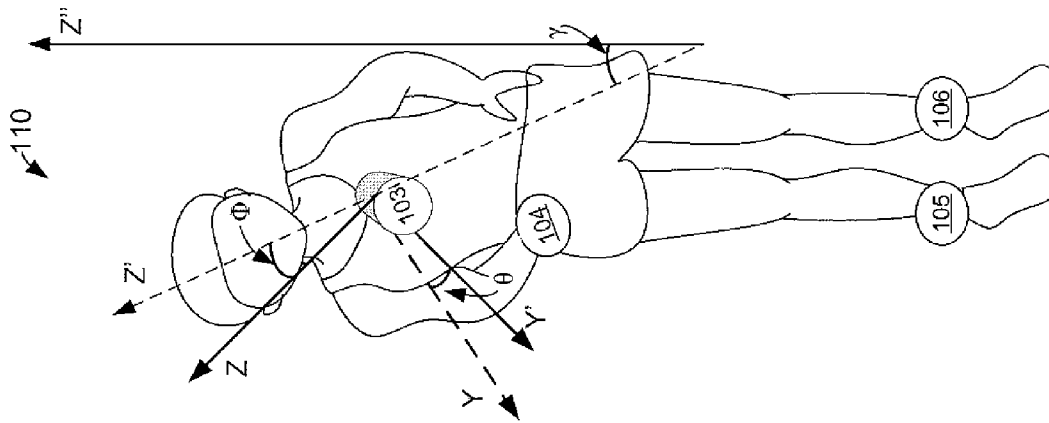


FIG. 5



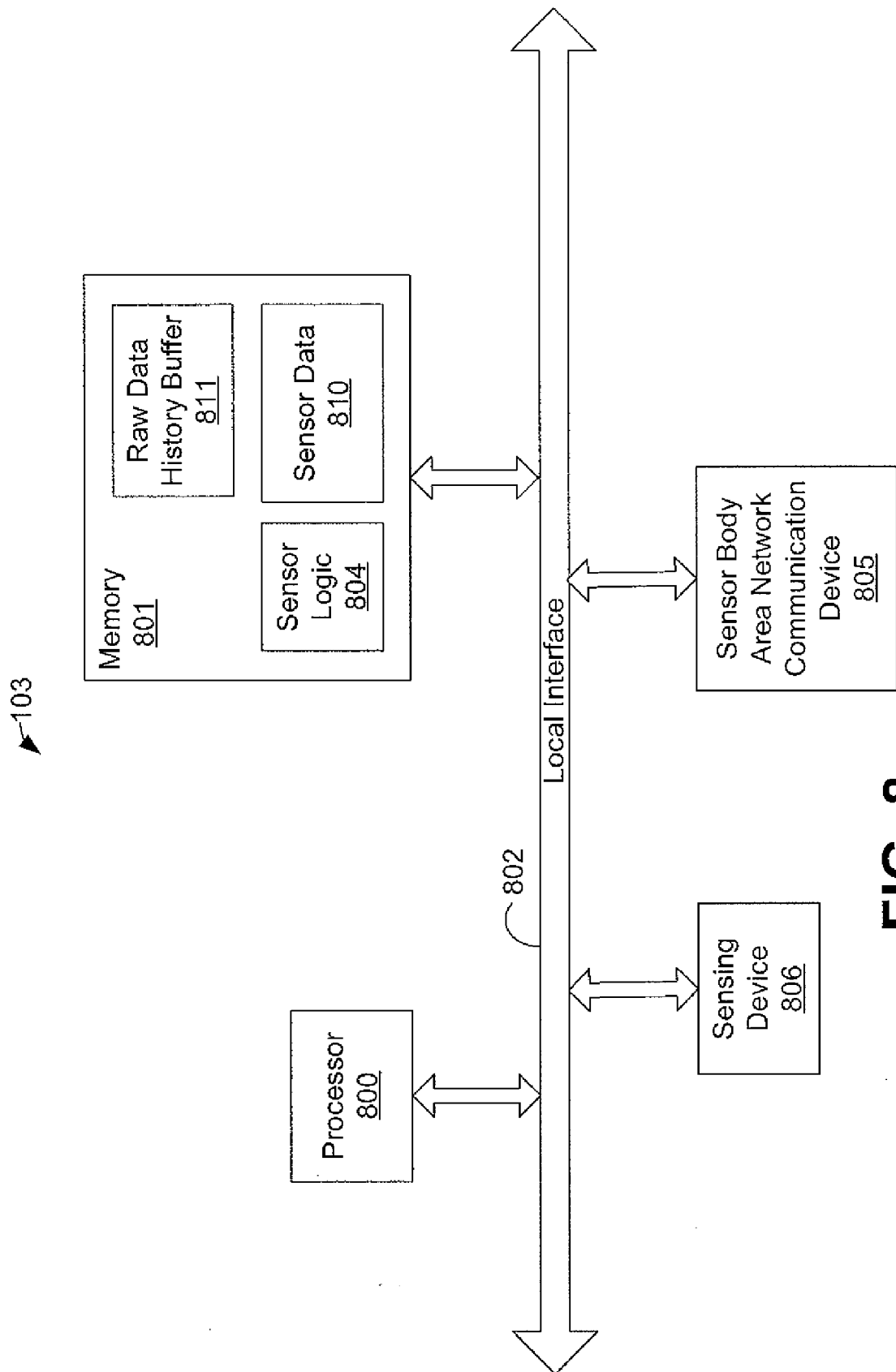


FIG. 8

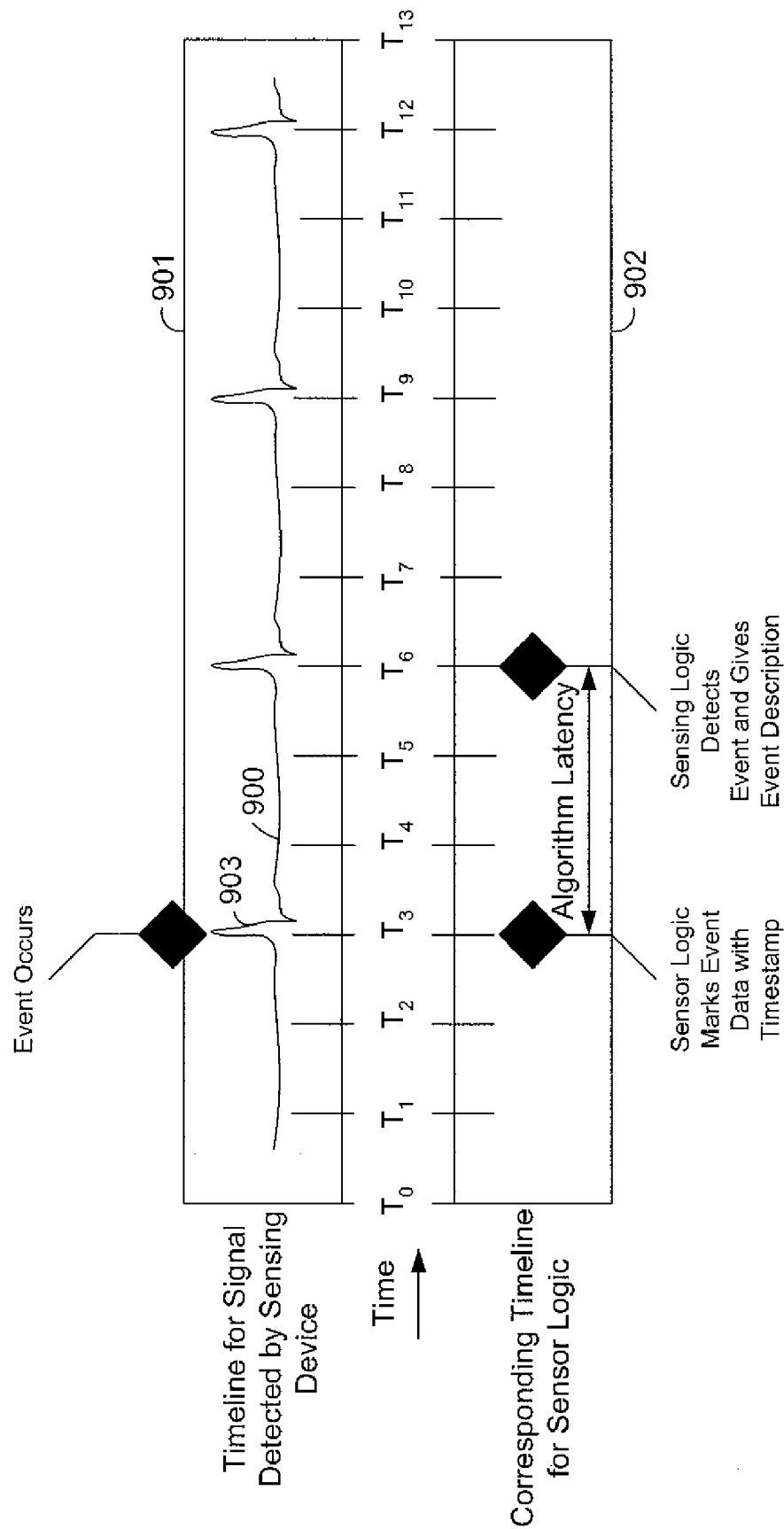


FIG. 9

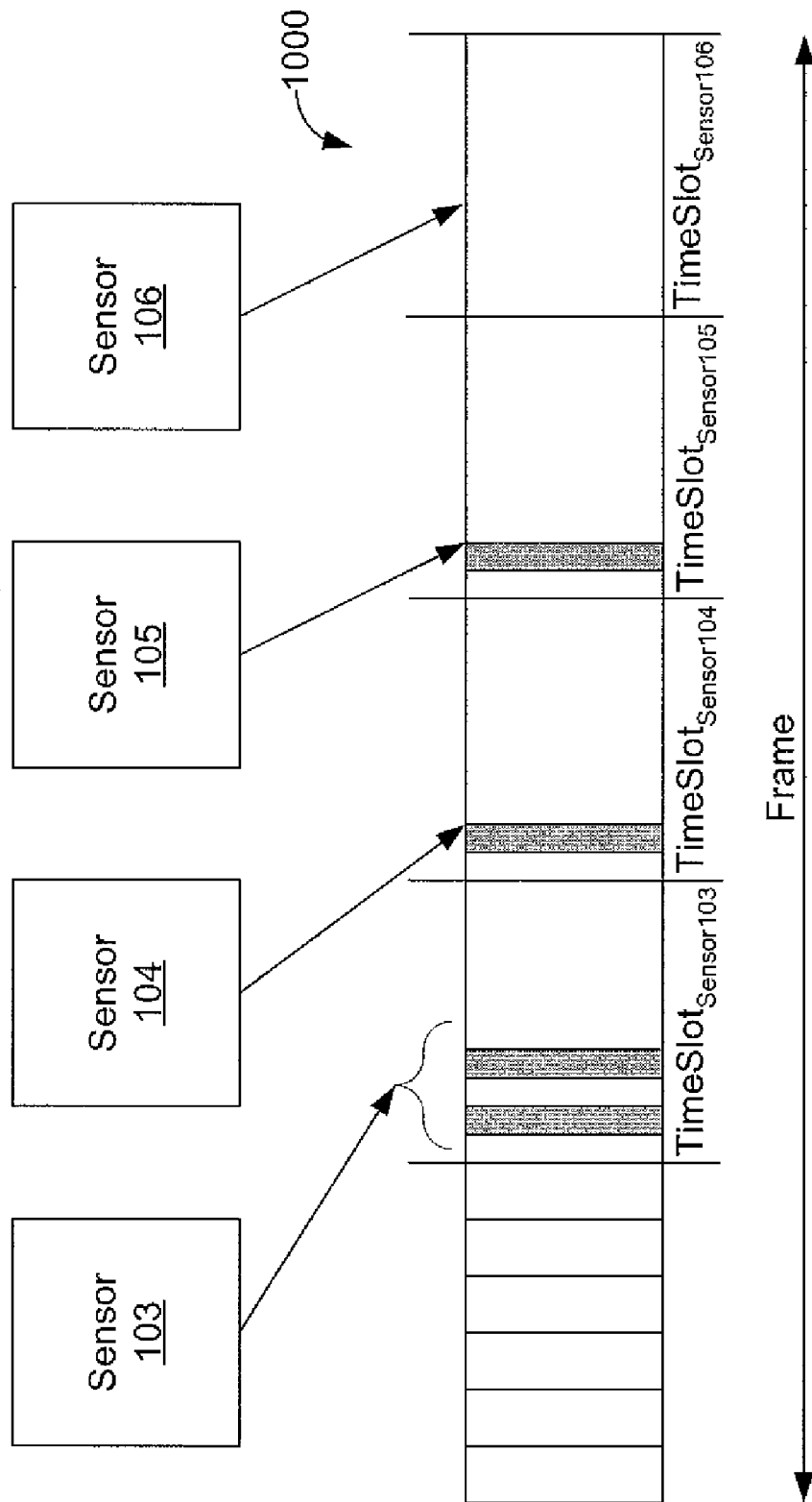


FIG. 10

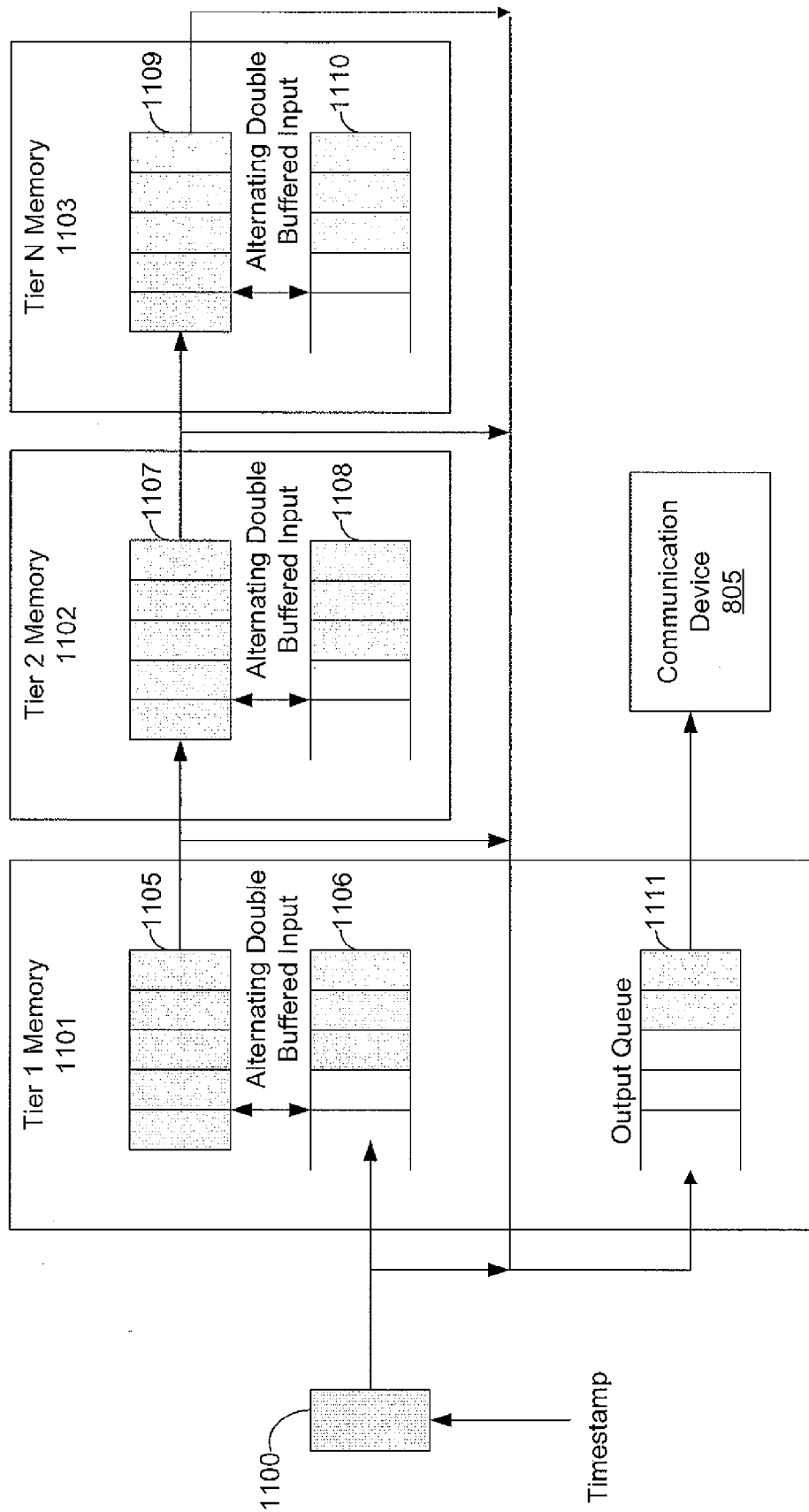


FIG. 11

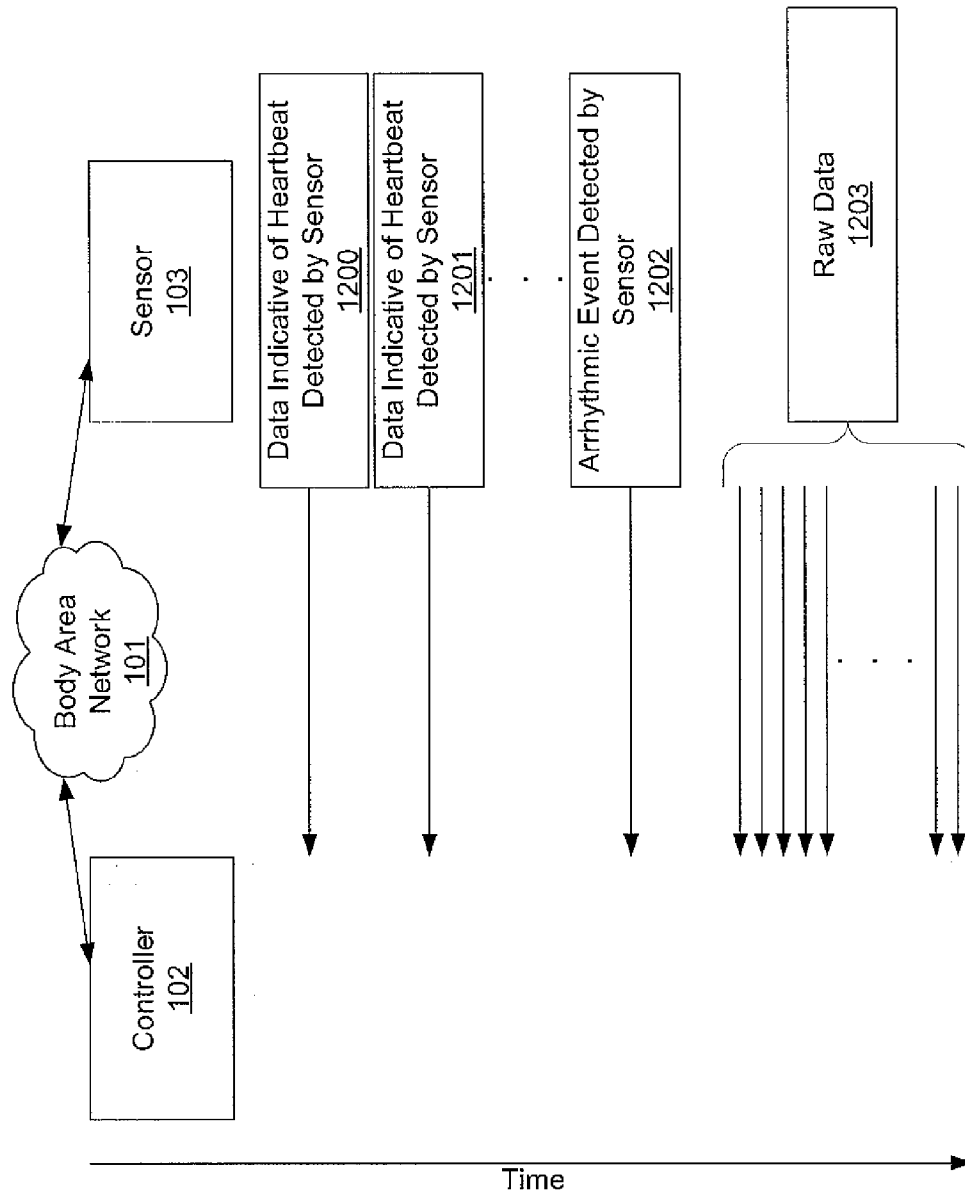


FIG. 12

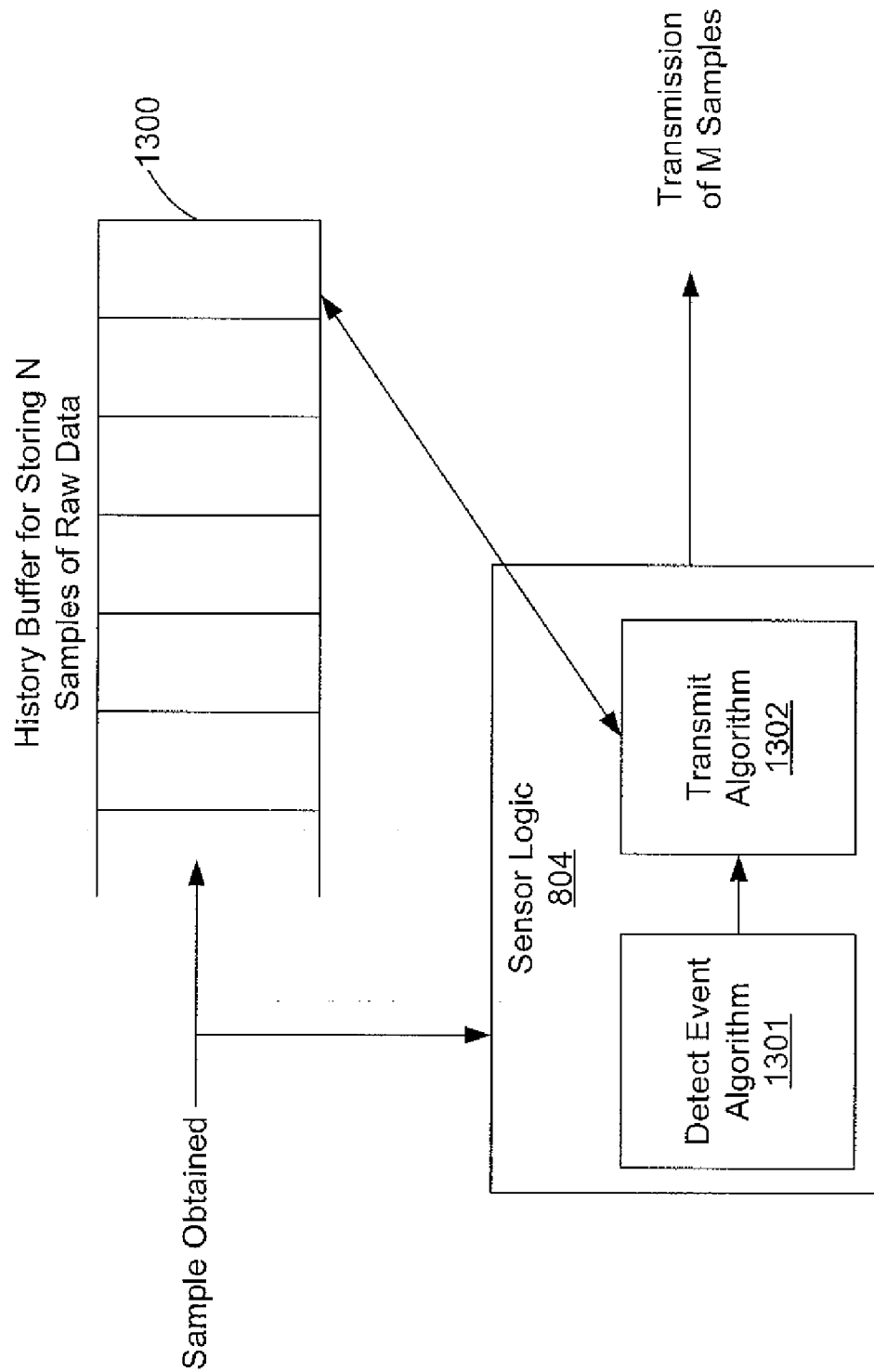


FIG. 13

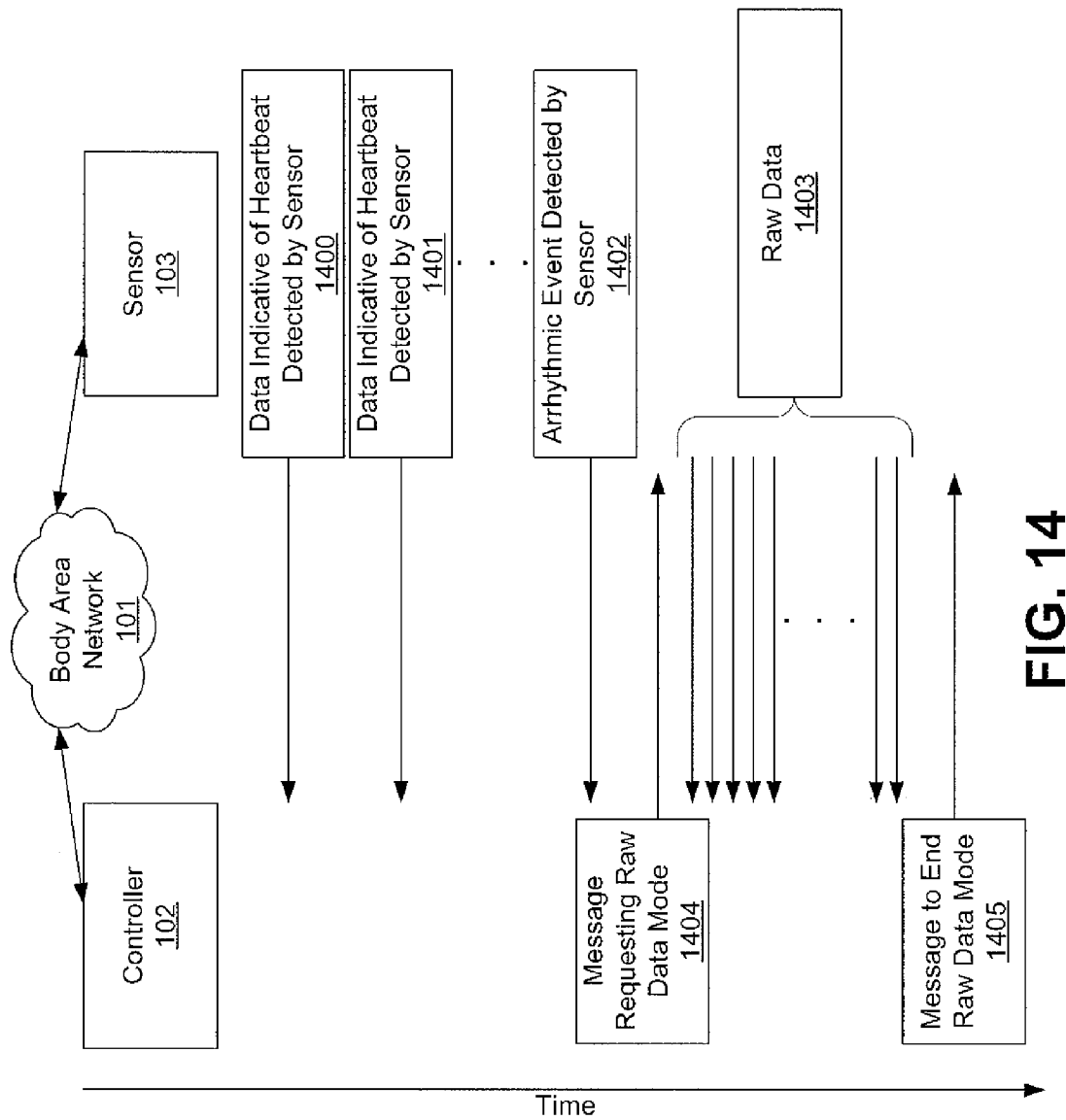


FIG. 14

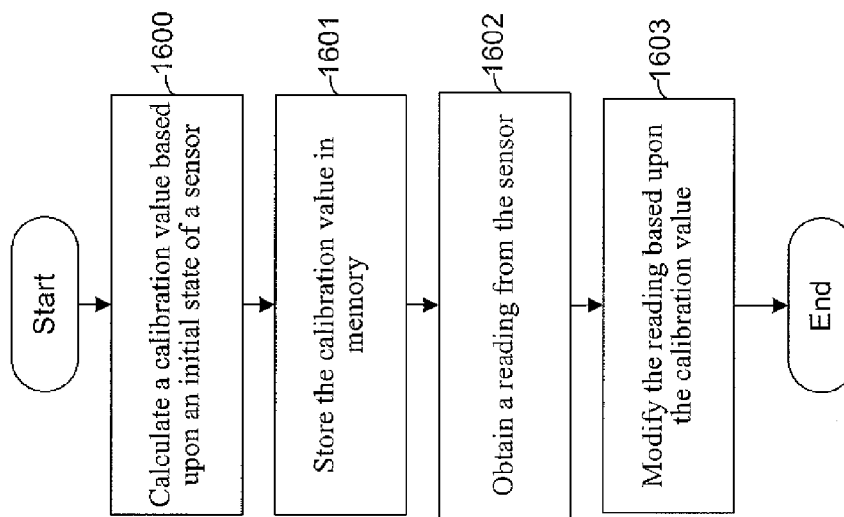


FIG. 15

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WIRELESS SENSOR NETWORK CALIBRATION SYSTEM AND METHOD

CROSS REFERENCE TO RELATED APPLICATION

[0001] This application claims priority to U.S. Provisional Application No. 60/884,352, entitled “Wireless Sensor Network System and Method for Using the Same,” filed on Jan. 10, 2007, which is incorporated herein by reference.

FIELD OF THE INVENTION

[0002] The present invention relates generally to the field of wireless sensor networks. In particular, the present invention relates to wireless sensor networks which monitor one or more external signals wherein a change in such signals triggers detection, monitoring, recording, and reporting functions of the system. More particularly, the present invention relates to a wireless sensor network system to be used for physiological health monitoring, environmental monitoring, industrial applications, machinery maintenance, and other complex networking environments.

BACKGROUND OF THE INVENTION

[0003] Wireless sensor networks are known in the field of computing. Such networks are used for detecting, monitoring, recording, and reporting signal changes specific to the application in which it is used. For example, in a physiological health monitoring application, a wireless sensor network may include accelerometer sensors for measuring motion and orientation; temperature and humidity sensors; electrodes and bio-amplifiers for measuring heart waveforms, respiration, and muscle activity; oxygen saturation (SPO₂) sensors; and galvanic skin response (GSR) sensors.

[0004] Wireless sensor networks are composed of one or more sensor nodes and a system controller. Sensor nodes include a computing platform with wireless communication capabilities and one or more sensor devices. The system controller provides a data sync point for the collection and extraction of data, system configuration capabilities, and may include an interface for the end user of the wireless sensor network. The system controller may be referred to as a personal server, network coordinator, or personal area network (PAN) coordinator. The system controller may provide visual, audible or other signals to the user in response to certain events.

[0005] “Events” refer to specific changes in signals such as heartbeat detection and health monitoring applications, temperature detection and environmental monitoring, or vibration at specified frequencies in industrial applications. Events can also be used to describe and extract complex features which require combining and analyzing results from multiple signals and sensors.

[0006] In resource constrained systems such as wireless sensor networks, nodes are battery powered, placing a premium on low power consumption. Furthermore, such nodes are often manufactured with unique identifiers, making placement of such nodes throughout the network in its desired application critical to its proper function in the system. Furthermore, a wireless sensor network may contain a plurality of sensor nodes, each producing various types of data, each requiring a different amount of power consumption and memory, and any of which may be important to the overall understanding of the system in which it is operating.

[0007] Prior art wireless sensor networks rely on complex central monitoring units and require complex signal processing in order to effectively manage data generated by the sensor nodes. It is desirable, therefore, to provide a wireless sensor network capable of reserving memory, controlling the delivery of contextual event data, and allowing for node discovery, configuration, and calibration in multi-node applications. Each of these capabilities is provided in the present invention.

SUMMARY OF THE INVENTION

[0008] The present disclosure is directed to a wireless sensor network capable of event management and memory conservation, contextual event data delivery, and node discovery configuration and calibration in multi-node applications.

[0009] A system in accordance with an embodiment of the present disclosure has at least one sensor and a controller communicatively coupled to the sensor. The system further has logic configured to calculate a calibration value based upon an initial state of the sensor and store the calibration value in memory.

[0010] A method in accordance with an embodiment of the present disclosure can be generally conceptualized by the following steps: 1) coupling a sensor to a body; communicatively coupling a controller to the sensor; and calculating a calibration value based upon an initial state of the sensor.

BRIEF DESCRIPTION OF THE DRAWINGS

[0011] The present invention is described with reference to the accompanying drawings.

[0012] FIG. 1 depicts a wireless sensor network system in accordance with an embodiment of the present disclosure.

[0013] FIG. 2 is a block diagram of an exemplary controller of the wireless sensor network system depicted in FIG. 1.

[0014] FIG. 3 is a drawing of a user's axes as used by a calibration function of the system depicted in FIG. 1.

[0015] FIG. 4 is a drawing of a user's axes and a sensor's axes as used by a calibration function of the system depicted in FIG. 1.

[0016] FIG. 5 is a drawing of a user's axes and a sensor's axes including the effect on the Z' axis of gravity as used by a calibration function of the system depicted in FIG. 1.

[0017] FIG. 6 is a drawing of a sensor's axes and a gravity vector as used by a calibration function of the system depicted in FIG. 1.

[0018] FIG. 7 is a drawing of a user's axes and the effect of the user's movement as used by a calibration function of the system depicted in FIG. 1.

[0019] FIG. 8 is a block diagram of an exemplary sensor of the wireless sensor network system depicted in FIG. 1.

[0020] FIG. 9 is a timeline depicting an algorithm latency illustrating event management as performed by the system of FIG. 1.

[0021] FIG. 10 is a block diagram of a data frame as used by the system of FIG. 1.

[0022] FIG. 11 is a block diagram of multi-tiered memory architecture as used by the system of FIG. 1.

[0023] FIG. 12 is a timeline illustrating the contextual data delivery functionality of the system of FIG. 1.

[0024] FIG. 13 is a block diagram illustrating the contextual data delivery function of the system of FIG. 1.

[0025] FIG. 14 is a timeline illustrating the contextual data delivery functionality of the system of FIG. 1.

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[0026] FIG. 15 is a flowchart of exemplary architecture and functionality of the calibration functionality of the sensor logic of the controller of the system of FIG. 1.

DETAILED DESCRIPTION

[0027] FIG. 1 depicts a wireless sensor network system 100 in accordance with an embodiment of the present disclosure. The system 100 comprises a plurality of sensors 103-106 coupled to a body 107 of a user 110. In addition, the system 100 comprises a controller 102 that is communicatively coupled to the sensors 103-107 via a body area network 101.

[0028] In one embodiment, the functional capabilities and the hardware (not shown) of the sensors 103-106 are characteristically homogenous. In another embodiment, the functional and hardware characteristics of each of the sensors 103-106 may differ. The sensors 103-106 include, for example, one or more accelerometer sensors for measuring motion and orientation, temperature and humidity sensors, electrodes and bio-amplifiers for measuring heart rate and heart waveforms, humidity sensors, respiration sensors, muscle activity sensors, SpO₂ sensors, and/or GSRs. These types of sensors are identified for exemplary purposes, and other types of sensors can be used in other embodiments of the wireless sensor network system 100.

[0029] Furthermore, four sensors 103-106 are shown coupled to the user's body 107 in FIG. 1. However, four is an exemplary and arbitrary number. More or fewer sensors 103-106 may be used in other embodiments of the wireless sensor network system 100.

[0030] As indicated hereinabove, the controller 102 is communicatively and wirelessly coupled to the plurality of sensors 103-106 through the body area network 101. The controller 102 performs certain initial functions, including discovery of available sensors 103-106, configuration of the sensors 103-106, and calibration of the system 100 related to orientation of the user's body 107. Note that the controller 102 may be, for example, a smart phone, an intelligent wrist watch, or a desktop appliance, such as a wireless gateway. Further note that a "smart phone" refers to a telephone that has data accessing features. As an example, a mobile telephone that has voice services in combination with Internet, e-mail, fax, and/or pager capabilities is referred to as a smart phone.

[0031] Once the controller 102 has performed the initial functions, the controller 102 receives data from the plurality of sensors 103-106 related to the physical and physiological aspects of the body 107 through the body area network 101. The data may be indicative, for example, of the present orientation of the body 107, the heartbeat waveform, humidity, oxygen saturation, muscle activity, and/or temperature.

[0032] Furthermore, the controller 102 may communicate audibly or visually information related to the sensors 103-106 to the user 110. For example, during the initial functions, the controller 102 may communicate commands to the user 110 related to placement of the sensors 103-106 on the user's body 107. The initial functions of discovery, configuration, and calibration are described further herein.

[0033] The controller 102 may be, for example, a hand-held device like a personal digital assistant (PDA) or any other type of device capable of communicating over the body area network 101 with the sensors 103-106. Accordingly, the controller 102 comprises software, hardware, or a combination thereof to perform a variety of functions. Such functions may include, for example, wireless communications, network

access, or the like. The controller 102 may be stylus-driven, keyboard driven, or voice driven. Alternatively, the controller 102 may be a personal computer that communicates wirelessly with the sensors 103-106. The controller 102 is described further with reference to FIG. 2.

[0034] The body area network 101 may be any type of body area network known in the art or future-developed. In one embodiment, the body area network 101 is implemented with Zigbee®. "Zigbee" refers a set of specifications for communication protocols for digital radios built around the Institute of Electrical and Electronic Engineers (IEEE) standard 802.15.4 wireless protocol.

[0035] In another embodiment, the body area network 101 is implemented with Bluetooth®. "Bluetooth" refers to another set of specifications for communication protocols for a personal area networks (PAN). Note that Zigbee and Bluetooth are exemplary communication protocols that can be used, and other communication protocols and specifications can be used in other embodiments of the body area network 101.

[0036] In one embodiment, the system 100 further comprises a medical server 109, which is communicatively coupled to the controller 102 via a network 108. The network 108 may be any type of network known in the art, including, for example, Ethernet, analog cellular, digital cellular, short range radio wireless, Wi-Fi, WiMax, broadband over power line, coaxial cable, and the like.

[0037] During operation, the controller 102 communicates with the plurality of sensors 103-106 to collect physical and/or physiological data related to the body 107 of the user 110. The data collected can be uneventful and historical in nature, and such data can be used to as a physical and/or physiological baseline for the user 110. In addition, the sensors 103-106 may also be triggered to perform specific data collection functions in response to an uncharacteristic event. Such data may be transmitted to the controller 102, and the controller 102 can, in turn, transmit the data collected in response to the event to the medical server 109.

[0038] In one embodiment, the medical server 109 may be monitored. Thus, in response to the uncharacteristic event, medical personnel may be alerted so that the user can obtain requisite medical attention. In another embodiment, the controller 102 relays information obtained from the sensors 103-106 to the medical server. In this regard, the medical server 109 may comprise a web portal (not shown), email and texting capabilities for interface with the user 110 and control of the system 100.

[0039] The wireless sensor network system 100 performs a variety of functions related to the acquisition and analysis of the data collected. These functions are described in more detail hereafter.

[0040] FIG. 2 depicts an exemplary controller 102 of the present disclosure. The exemplary controller 102 generally comprises processor 200, display device 203, input device 206, network device 207, and controller body area network communication device 205. Each of these components communicates over local interface 202, which can include one or more buses.

[0041] Controller 102 further comprises control logic 204 and controller sensor data 210. Control logic 204 and sensor data 210 can be software, hardware, or a combination thereof. In the exemplary controller 102 shown in FIG. 2, control logic 204 and sensor data 210 are shown as software stored in memory 201. Memory 201 may be of any type of memory

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known in the art, including, but not limited to random access memory (RAM), read-only memory (ROM), flash memory, and the like.

[0042] As noted hereinabove, control logic 204 and sensor data 210 are shown in FIG. 2 as software stored in memory 201. When stored in memory 201, control logic 204 and sensor data 210 can be stored and transported on any computer-readable medium for use by or in connection with an instruction execution system, apparatus, or device, such as a computer-based system, processor-containing system, or other system that can fetch the instructions from the instruction execution system, apparatus, or device and execute the instructions.

[0043] In the context of the present disclosure, a “computer-readable medium” can be any means that can contain, store, communicate, propagate, or transport the program for use by or in connection with the instruction execution system, apparatus, or device. The computer readable medium can be, for example but not limited to, an electronic, magnetic, optical, electromagnetic, infrared, or semiconductor system, apparatus, device, or propagation medium.

[0044] Processor 200 may be a digital processor or other type of circuitry configured to run the control logic 204 by processing and executing the instructions of the control logic 204. By way of example, the processor 200 may be an Advanced RISC Machine ARM 7, ARM 9, Intel® PXA901, Intel 80386, Freescale® HCx08, Freescale® HCx11, Texas Instruments® MSP430, or a digital signal processor (DSP) architecture. Note that RISC refers to “Reduced Instruction Set Computer.” The processor 200 communicates to and drives the other elements within the controller 102 via the local interface 202.

[0045] In addition, controller body area network communication device 205 may be, for example, a low-powered radio device, e.g., a radio semiconductor, radio frequency antenna (RF antenna) or other type of communication device, which communicatively couples the controller 102 with the sensors 103-106 (FIG. 1). The control logic 204 communicates bi-directionally through the controller body area network communication device 205 with the plurality of sensors 103-106.

[0046] The display device 203 is a device for visually communicating information to the user 110 (FIG. 1). The display device 203 may be, for example, a backlit liquid crystal display (LCD) screen (not shown), which is touch-sensitive for operation with a stylus (not shown). Other types of display devices may be used in other embodiments of the present disclosure.

[0047] An operating system 211, which may be, for example, Windows Mobile®, may display data, including commands, to the user 110 (FIG. 1) via a series of graphical user interfaces (GUIs) (not shown). The GUIs may comprise a plurality of scalable windows (not shown) that display, for example, data indicative of commands or analysis of information.

[0048] Controller sensor data 210 includes any data stored on the controller 102 related to the system 100 (FIG. 1), including data related to the sensors 103-106. Such sensor data 210 may include, for example, data indicative of particular readings or historical data of a plurality of readings received from one or more of the sensors 103-106 (FIG. 1). In addition, sensor data 210 may include configuration data specific to the user 110 that is using the controller 102.

[0049] Note that a “reading” refers to any data that is received from the sensors 103-106 that represents physical or physiological characteristics of the body 107 (FIG. 1) of the user 110. As described further herein, a reading may be requested from a sensor 103-106 by the controller 102 or a reading may be transmitted at a particular time interval predetermined for the particular sensor 103-106 from which the controller 102 is requesting data.

[0050] The input device 206 enables the user 110 to enter data into the controller 102. In one embodiment, the input device 206 is a keyboard, and the user 110 uses the keyboard to type data into the handheld, which can be stored as sensor data 210, described hereinabove. In addition, the display device 203 may be a touch screen (not shown), and the controller 102 may comprise a stylus (now shown) that the user 110 can use to enter data via the touch screen (not shown).

[0051] In one embodiment, the controller 102 may comprise a speaker device 204 and a microphone 212. In such an embodiment, the controller 102 may audibly communicate commands and/or information to the user 110 via the speaker device 204. Furthermore, the user 110 may provide information to the controller 102 by speaking into the microphone 212.

[0052] During operation, the control logic 204 configures the system 100. In one embodiment, the user 110 may take some controller-directed action, e.g., placing sensors on the body 107, however, in other embodiments, the control logic 204 can autonomously discover the sensors 103-106 without action by the user 110.

[0053] In this regard, the control logic 204 initially discovers the sensors 103-106 that are proximate to the controller 102 for use in the body area network 101. To discover the sensors 103-106, the control logic 204 broadcasts a wireless discovery message. A “wireless discovery message” refers to a message that can be transmitted through the body area network 101 (FIG. 1) by the control logic 204 through the controller body area network communication device 205. This message is received by the sensors 103-106 and handled by each sensor 103-106 accordingly. Communication protocols, e.g., Zigbee® and Bluetooth®, define such a wireless discovery message. Notably, however, any type of communication protocol known in the art that includes a wireless discovery message may be used in other embodiments.

[0054] As an example, the wireless discovery message, by its particular format, may request all sensors 103-106 that receive the wireless discovery message to respond. In one embodiment each sensor 103-106 transmits, in response to the wireless discovery message, data indicative of its unique hardware address associated with the responding sensor 103-106. Thus, the control logic 204 can uniquely identify each discovered sensor.

[0055] Upon receipt of a response from each sensor 103-106, the control logic 204 stores as controller sensor data 210 data indicative of each responding sensor 103-106 and their corresponding hardware address. Once the discovery process is complete, the control logic 204 has identified sensors 103-106 by their corresponding hardware address and stored controller sensor data 210 reflecting the characteristics of each sensor 103-106.

[0056] Once the control logic 204 discovers the sensors 103-106 available to the system 100, the control logic 204 assigns to each sensor a logical function within the body area network 101. Given a homogeneous set of wireless sensors 103-106 with sufficiently similar capabilities, such that any

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two sensors 103-106 can be interchanged, the control logic 204 prompts the user 110 to place the sensors 103-106 on the body 107. In one embodiment, the control logic 204 may prompt the user 110 visually via a graphical user interface (GUI) displayed to the display device 203. In another embodiment, the control logic 204 may prompt the user 110 audibly via the speaker device 204. Other prompts may be used to instruct the user 110 to place the sensors 103-106 on the body 107 in other embodiments.

[0057] The control logic 204 prompts the user 110 in sequence to place a sensor 103-106 on the body 110 in a specified location. As an example, the control logic 204 may prompt the user with the following command: "Place a sensor on your chest." In one embodiment, each sensor 103-106 comprises an accelerometer (not shown) for motion sensing. Thus, the user 110 need not know the identity of the sensor the user 110 selects. Instead, the control logic 204 monitors the sensors 103-106 thereby autonomously requesting measures of movement, and control logic 204 detects which sensor 103-106 is experiencing the greatest movement based upon the measures received. In this regard, the user 110 is free to select a sensor 103-106 at random and place it in the location identified in the command. The control logic 204 then associates the hardware address with the location in the sensor data 210.

[0058] The control logic 204 then prompts the user 110 with another command: "Place a sensor on your right wrist." Again, the control logic 204 detects movement of the sensor 103-106 that is being placed, and records as sensor data 210 the hardware address associated with the moving sensor 103-106 with the location identified in the command. The control logic 204 continues this process until each of the sensors 103-106 discovered during the discovery process is placed on a location on the body 107 of the user 110.

[0059] In one embodiment, during assignment of sensors 103-106 with body locations, the control logic 204 dynamically reconfigures each sensor 103-106 to perform a function specific to the location on which the sensor 103-106 was placed. For example, the sensor 103-106 that is placed on the chest is dynamically reconfigured, for example, to monitor heart rate. As another example, the sensor 103-106 that is placed on the wrist is reconfigured, for example, to monitor oxygen saturation. In this regard, the control logic 204 transmits commands to the sensors 103-106 specifying particular algorithms to use. The control logic 204 also can transmit wireless firmware upgrades of each sensor 103-106.

[0060] In another embodiment, the control logic 204 completes the assignment process prior to reconfiguring the sensors 103-106. Once assignment of each sensor 103-106 to a particular location is complete, the control logic 204 reconfigures each sensor 103-106 to perform a function specific to the location on which the sensor 103-106 is placed.

[0061] In another embodiment, the control logic 204 also transmits information for dynamically reloading a microprocessor (not shown), which is part of the sensor 103-106. In this regard, the system 100 is resource-constrained, and it may be difficult for each sensor 103-106 to include each possible algorithm that might be needed based on an arbitrary location assignment as described hereinabove. In this case, the control logic 204 dynamically reloads the microprocessor instruction code to implement the desired function associated with the location arbitrarily selected by the user 110 for the particular sensor 103-106.

[0062] In another embodiment of the system 100, the sensors 103-106 may incorporate temperature sensors (not shown). The control logic 204 may obtain data from the sensors 103-106 indicative of the temperature increased realized by placing the sensor 103-106 on the body 107. The control logic 204 may use the temperature increase to determine which sensor 103-106 has been placed on a particular location on the body 107.

[0063] In another embodiment of the system 100, the sensors 103-106 use integrated electrodes for radiating the human body. When in contact with the skin, a small charge will generate a small current through the human skin, thus effectively measuring skin or body impedance. This current is detectable by the sensor 103-106, and the control logic 204 can determine that the sensor 103-106 is now in contact with human skin.

[0064] In another embodiment of the system 100, sensor discovery and assignment are an integrated function. This is especially useful if the sensors 103-106 are allowed to enter a low power state when not in use. In this case, the sensors 103-106 will originate communications with the control logic 204 of the controller 102 once they recognize an in-use event such as being placed on the body 107. An in-use event can be detected by the control logic 204 by listening for messages received from the sensors 103-106 and interpreting those messages received.

[0065] In addition to performing discovery and configuration of the system 100, the control logic 204 further performs calibration of the system 100. As described hereinabove, one or more of the sensors 103-106 may be used to determine a user's orientation or position through accelerometers. For example, data obtained from accelerometers on one or more sensors 103-106 may be used to indicate whether the user 110 is in a supine position or standing in an upright position.

[0066] Thus, in one embodiment of the present disclosure, the control logic 204 self-calibrates the system 100 to compensate for any offset caused by the placement of the sensors 103-106 on the user's body. Notably, it is the orientation of the user 110 wearing the sensors 103-106 in the system 100 that is relevant for determining movement of the user 110. However, placement of the sensors 103-106, because placement is arbitrary, may tend to effect readings made with respect to movement by skewing orientation of the actual user 110. Therefore, the control logic 204 calculates and calibrates a relative orientation.

[0067] As described hereinabove, the control logic 204 performs calibration to ensure that sensor readings for detecting movement are accurate in light of the placement of sensors 103-106 on the body 107 of the user 110. Calibration is now described in more detail with reference to FIGS. 3-7. To perform calibration, the control logic 204 instructs the user 110 to stand in an upright position, communicating with the user 110 as described hereinabove. When the user 110 is requested to stand in an upright position, the control logic 204 assumes that the user's body 107 is oriented along the X', Y' and Z' axes as shown in FIG. 3.

[0068] The control logic 204 then determines the actual orientation of the sensors 103-106 and calculates a calibrating correction factor. With reference to FIG. 4, the sensor 103 is shown as placed upon the chest area of the body 107. The sensor 103 is shown as rotated forward about the Y axis creating two angle offsets: θ (angle between the sensor's X axis and the user's X' axis) and Φ (angle between the sensor's Z axis and the user's Z' axis). The control logic 204 calculates

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the calibration angles θ and Φ by applying a theorem that the static effects of gravity will only affect the Z' axis in a magnitude of 1 g.

[0069] Thus, with reference to FIG. 5, gravity vector 500 represents the effect of gravity relative to the sensor's axis system (X', Y', and Z'). Further, FIG. 6 depicts the gravity vector 600 as it relates to the sensor 103. Therefore, the control logic 204 can calculate the angles θ and Φ by receiving measurements from the sensor 103 in the X direction and the Z direction and calculating as follows:

$$\theta = \sin^{-1}\left(\frac{x_{\text{measured}}}{1g}\right)$$

$$\phi = \cos^{-1}\left(\frac{z_{\text{measured}}}{1g}\right)$$

[0070] Once the angles θ and Φ are calculated, the control logic 204 can use the calculated offset angles θ and Φ to determine the orientation of the body 107 of the user 110 as the body 107 moves. In this regard, as the body 107 moves, the control logic 204 obtains new measurements from one or more sensors 103-106, and the control logic 204 uses the offset angles θ and Φ to calculate the orientation of the body 107 as it moves.

[0071] Thus, as an example, with reference to FIG. 7, the user 110 moves his body 107 and creates an angle, γ , between the original calibrated Z' axis and true vertical Z'' axis. The control logic 204 can calculate γ from the sensor measurements as follows:

$$\gamma = \cos^{-1}\left(\frac{z_{\text{measured}}}{1g}\right) - \phi$$

[0072] Note that any of the axes X', Y', and Z' may have associated with it an initial offset depending upon the location of the sensor 103-106 (FIG. 1). Only an offset θ and Φ in relation to the X' and Z', respectively, are shown calculated in the example provided hereinabove. However, in addition, there may also be an offset Ω corresponding to the Y' axis. Furthermore, FIG. 7 illustrates a calculation of only an angle γ for the Z' axis, however angles α and β may be calculated for angles corresponding to X' and Y', respectively.

[0073] Notably, given three initial offsets θ , Ω , and Φ with respect to the X', Y', and Z' axes respectively, the user's angles of orientation α , β , and γ with respect to X', Y', and Z' respectively can be calculated as follows:

$$\alpha = \sin^{-1}\left(\frac{x_{\text{measured}}}{1g}\right) - \theta$$

$$\beta = \sin^{-1}\left(\frac{y_{\text{measured}}}{1g}\right) - \Omega$$

$$\lambda = \cos^{-1}\left(\frac{z_{\text{measured}}}{1g}\right) - \phi$$

[0074] This method is directly applicable to cases where sensor nodes are placed upside down (180 degree rotation). This method is also extensible to other zero-state configurations (other than standing) such as sitting, lying, or combination of multiple initial state calibrations.

[0075] Furthermore, the sensor 103-106 for detecting motion may also be subject to a wide range of factors, which could degrade performance. Notably, temperature, humidity, and power supply voltage can affect sensor performance. When affected by such factors, the control logic 204 may determine the actual affect of the relevant factor, e.g., temperature, and define a transfer function for describing the sensor readings when the sensor 103-106 is affected. When defining a transfer function is possible, other sensors (not shown) can be used to collect information for the transfer function so that the control logic 204 can compensate for the affects as these factors may vary over time and change after the initial calibration.

[0076] As an example, an ambient air temperature sensor (not shown) could be used to obtain varying temperature readings. The control logic 204 can use these varying temperature readings with the transfer function defined in order to compensate for the affects of the varying temperature. In addition, the same method could be used with a humidity sensor to compensate for degradation of the motion sensor 103-105 as a function of humidity, and a voltage measuring sensor to compensate for degradation of the motion sensor as a function of supply voltage.

[0077] FIG. 8 depicts an exemplary sensor 103 of the present disclosure. As indicated hereinabove, in one embodiment the sensors 103-106 are substantially similar. In this regard, the sensors 103-106 may be characteristically homogeneous, however if they differ, they could differ in the type of sensing hardware employed and/or the software employed to collect the data. For purposes of brevity, only sensor 103 is discussed hereinafter. However, the other sensors 103-106 behave substantially similar.

[0078] The exemplary sensor 103 generally comprises processor 800, a sensing device 806, and sensor body area network communication device 805. Each of these components communicates over local interface 802, which can include one or more buses.

[0079] Sensor 103 further comprises sensor logic 804 and sensor data 810. Sensor logic 804 and sensor data 810 can be software, hardware, or a combination thereof. In the exemplary sensor 103 shown in FIG. 8, sensor logic 804 and sensor data 810 are shown as software stored in memory 801. Memory 801 may be of any type of memory known in the art, including, but not limited to random access memory (RAM), read-only memory (ROM), flash memory, and the like.

[0080] As noted hereinabove, sensor logic 804 and sensor data 810 are shown in FIG. 8 as software stored in memory 801. When stored in memory 801, sensor logic 804 and sensor data 810 can be stored and transported on any computer-readable medium for use by or in connection with an instruction execution system, apparatus, or device, such as a computer-based system, processor-containing system, or other system that can fetch the instructions from the instruction execution system, apparatus, or device and execute the instructions.

[0081] In the context of the present disclosure, a "computer-readable medium" can be any means that can contain, store, communicate, propagate, or transport the program for use by or in connection with the instruction execution system, apparatus, or device. The computer readable medium can be, for example but not limited to, an electronic, magnetic, optical, electromagnetic, infrared, or semiconductor system, apparatus, device, or propagation medium.

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[0082] Processor **800** may be a digital processor or other type of circuitry configured to run the sensor logic **804** by processing and executing the instructions of the sensor logic **804**. By way of example, the processor **800** may be an Advanced RISC Machine (ARM) 7, ARM 9, Intel® PXA901, Intel 80386, Freescale HCx08, Freescale® HCx11, Texas Instruments® MSP430, or a digital signal processor (DSP) architecture. Note that RISC refers to “Reduced Instruction Set Computer.” The processor **800** communicates to and drives the other elements within the sensor **103** via the local interface **802**.

[0083] In addition, sensor body area network communication device **805** may be, for example, a low-powered radio device, e.g., a radio semiconductor, radio frequency antenna (RF antenna) or other type of communication device, that communicatively couples the sensor **103** with the controller **102** (FIG. 1). The sensor logic **804** communicates bi-directionally through the sensor body area network communication device **805** with the controller **102**.

[0084] The sensing device **806** may be, for example, heart waveforms sensors, respiration sensors, and muscle activity sensors, SpO₂ sensors, and/or GSR sensors. Further, the sensing device **806** may be an electrode for detecting current from the skin (not shown) of the body **107**. These are exemplary types of sensing devices, however, other types of sensing devices may be used in other embodiments of the present disclosure.

[0085] Sensor data **810** refers to data related to the sensing device **806**. In this regard, the sensor data **810** may be, for example, data indicative of readings received from the sensing device **806**. In addition, sensor data **810** may encompass configuration data specific to the user **110** (FIG. 1) that is using the controller **102** (FIG. 1) and the sensor **103**.

[0086] In one embodiment, the controller **102** (FIG. 1) and the sensor **103** work in conjunction to perform event management and contextual event data delivery. Event management refers to the receipt, storage, and identification of data indicative of an event. An “event” refers to an occurrence evidenced by a change in data detected by the sensing device **806**.

[0087] In one embodiment, in order to accomplish event management, the sensor logic **804** assesses a timestamp for each reading obtained by sampling a signal received by the sensing device **806**. The data that receives the timestamp is not immediately transmitted to the controller **102** (FIG. 1). Instead, the sensor logic **804** defers transmission of the data until the particular sensor’s assigned transmission interval. Such time-stamped data indicative of the reading is stored as sensor data **810**, and such timestamp is associated with the reading prior to any on-sensor operations performed on the reading to determine whether an event has occurred.

[0088] In addition, the sensor logic **804** performs contextual data delivery. “Contextual data delivery” refers to the transmission of data related to an event, as described hereinabove, to the controller **102**.

[0089] In one embodiment in order to perform contextual data delivery, the sensor logic **804** stores raw data in a raw data history buffer **811**. Further, the sensor logic **804** performs operations on the data stored in the raw data history buffer **811** to determine if an event has occurred. As an example, a sensing device **806** may be configured to detect an analog heart rate signal, and the sensing device **806** samples the signal periodically to obtain a reading. Once a reading is obtained, the sensor logic **804** stores the raw data indicative of the reading in the buffer **811**. The sensor logic **804** may

analyze a plurality of readings over a pre-determined time period, for example five minutes. If there is a sharp increase in the value of the reading, this may indicate an event. Thus, the sensor logic **804**, after its analysis to determine that an event may have occurred, may transmit the raw data in the buffer **811** to the controller **102**.

[0090] In another embodiment, the sensor logic **804** transmits readings and associated timestamps to the controller **102**. The controller **102** detects an event and transmits a message to the sensor **103** to enable raw data mode thereby allowing the sensing logic **806** to continually transmit raw data from the history buffer **811** to the controller **102** until the pertinent event has expired.

[0091] To further illustrate event management performed by the sensor **103** and the controller **102**, FIG. 9 depicts a timeline **901** and a corresponding timeline **902**. Timeline **901** depicts a signal **900** received by the sensing device **806** (FIG. 8) over time, T_0 to T_{13} . Timeline **902** depicts functionality of the sensor logic **804** over time, T_0 to T_{13} .

[0092] In the illustration, the sensor **103** detects a change in the monitored signal **900** (event) such as environmental data, physiological data, or machine health data. Such a change is evidenced by a spike **903** in the monitored signal **900**. Based on a network time reference, the sensor logic **804** assesses an “original timestamp” to the event occurrence at T_3 when the spike **903** occurs. The original timestamp is prior to any on-sensor processing time, independent of latency in utilizing any on-sensor resource (memory or other), and independent of network transmission time which can vary widely depending on the organization of the network and the variability inherent in heterogeneous networks. Notably, at time T_6 the sensor logic **804** detects the event and gives the event description. However, algorithm latency has occurred prior to the detection and description.

[0093] When the event detection algorithms require some finite execution time, as illustrated, the timestamp provided by the sensor logic **804** is independent of algorithm latency. Thus, in one embodiment, the sensor logic **804** assesses timestamps to each data point of sampled signal **900**. When the sensor logic **804** determines the occurrence of an event, the earlier data point timestamp (assessed on the original data point) can be used as the timestamp for the occurrence of the event.

[0094] In one embodiment, the control logic **204** (FIG. 2) of the controller **102** (FIG. 1) assigns specific time intervals for each sensor’s respective transmission or receptions. FIG. 10 depicts a block diagram of a communication frame **1000** in accordance with such an embodiment.

[0095] The exemplary communication frame **1000** assumes the sensors **103-106** (FIG. 1) are all-inclusive of those sensors in the body area network **101** (FIG. 1) for the example. Each sensor **103-106** collects data related to the signals that each sensor monitors. In one embodiment, the control logic **204** (FIG. 2) defines the frame **1000** to encompass a node command block, which can include binary digits reflecting a command to one or more of the sensors **103-106**. In addition, the control logic **204** defines a block of time slots $\text{TimeSlot}_{\text{sensor}103}$ - $\text{TimeSlot}_{\text{sensor}106}$. Notably, the control logic **204** would define a timeslot for transmission and reception for each sensor **103-106** in the node. In the example used throughout the present disclosure, four sensors **103-106** are shown in the body area network **101**. Thus, for continuity, four sensors **103-106** are used in the example provided in FIG. 10.

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[0096] In such an embodiment, the control logic 204 assigns a $\text{TimeSlot}_{\text{sensor103}}$ to the sensor 103, which may be a heart beat sensor. In addition, the control logic 204 assigns $\text{TimeSlot}_{\text{sensor104}}$ to the sensor 104, which may be a motion sensor.

[0097] Thus, an event occurs, for example a heart beat event occurs, which is detected by sensor 103, and a step event occurs, which is detected by sensor 104. The sensors 103 and 104 do not immediately transmit data to the controller 102 indicative of the heartbeat and step events. Instead, the sensors 103 and 104 wait until their respective time slots occur, and transmit the data during their respective time slots.

[0098] As described hereinabove, the event descriptions can be time stamped by the sensor logic 306 as they occur so as to not incur latency and jitter from deferred transmission artifacts. This allows faithful reproduction of the original events with proper timestamps independent of the actual transmission time.

[0099] Such an embodiment may require a synchronized network time reference, as described hereinabove. Thus, each sensor 103-106 and the controller 102 operate from a synchronized clock cycle. Thus, each sensor 103-106 knows when its corresponding time slot is ready for transmission and/or reception. In such an embodiment, a synchronization protocol, e.g., the Flooding Time Synchronization Protocol (FTSP), can be used to distribute a common time reference.

[0100] In another embodiment of the wireless sensor network system 100, reliability of the network transmission is not guaranteed. Sensors 103-106 can lose power, intermediate nodes (not shown) in multi-hop networks may exit without warning, in mobile networks the network topology can change without warning or leave range entirely, or outside factors may impair the ability of the wireless media to perform as expected. These conditions can be detected so that the sensor logic 804 can maintain the state of the network 101. Reliability and performance are improved when the sensors 103-106 perform autonomous detection of network changes.

[0101] In one embodiment, the controller 102 transmits periodic beacon messages. The sensor logic 804 receives the beacon messages from the controller 102 via the sensor body area communication device 805, and infers successful connectivity with the controller 102 by receipt of the periodic beacon message. When the beacon message arrives in a timely fashion, the sensor logic 804 can assume the network is operable; conversely when an allowable time period expires without beacon arrival, the sensor logic 804 can assume that the network is inoperable.

[0102] In another embodiment, the control logic 204 transmits an explicit acknowledgement message to verify that a message transmitted from the sensor 103-106 has been received by the controller 102 (FIG. 1). Thus, if the message is lost by an intermediate node (not shown) in the network 101 where the network 101 supports one hop or multi-hop transmission, the sensor logic 804 does not receive the acknowledgement message. In such a scenario, the sensor logic 804 employs a timeout mechanism that determines that the acknowledgement message did not arrive and behaves accordingly. Note that it is possible for one or more messages to be en route at any given time and the messages (or events) must be preserved as sensor data 810 (FIG. 8) on the sensor 103-106 and cannot be retired until the message or messages are acknowledged.

[0103] FIG. 11 depicts a memory hierarchy for a sensor 103-106 (FIG. 1) and illustrates another embodiment of an

event management method. In one embodiment of the system 100 (FIG. 1), the sensor logic 804 (FIG. 8) minimizes latency by transmitting event data when the event occurs. Based on autonomous detection of network changes, as described hereinabove, data indicative of events are stored in memory 801 (FIG. 8) for immediate transmission or for buffering to raw data history buffer 811 (FIG. 8).

[0104] In memory constrained systems, the available memory may have varying costs in terms of power and time latency such that the memory devices can be arranged hierarchically in order of preference. Moreover, events should first be buffered in the lowest penalty memory device, and, only on exhaustion of this resource, begin buffering in the next lowest penalty memory device, and so on. As an example, the sensor logic 804 can store the data in memory 801 hierarchically from lowest penalty to highest penalty, for example as follows: on-chip RAM, off-chip RAM, on-chip flash, off-chip flash. One embodiment places value on minimizing latency in delivering messages to the controller 102. The sensors 103-106 may be memory-constrained and comprise multi-tiered memory components, including an output queue 1111, "Tier 1 Memory" 1101, "Tier 2 Memory" 1102 through "Tier N Memory" 1103.

[0105] It is recognized that in real-time applications the memory devices 1101, 1102, and 1103 may incur time penalties for storage and retrieval. As a non-limiting example, flash memory may be employed with erase and program times measured in tens or even hundreds of milliseconds. When the application cannot tolerate this latency, a method for overlapping the operations is employed so that lowest penalty memory device is always available for event buffering. This is accomplished by using a double buffered approach at each tier in the memory hierarchy. Thus, at each tier 1101-1103 double buffers 1105/1106, 1107/1108, and 1109/1110 are maintained.

[0106] During operation, when a threshold number of events is reached, a block of events are moved, i.e., copied, to next tier storage while still maintaining a separate first-tier resource buffer for subsequent events that occur prior to completion of the move. The depth of the buffers 1105 and 1107 is selected to accommodate the maximum rate of event occurrence given the worst-case latency on the memory device. In one embodiment, the size of the buffers 1105 and 1107 is chosen for efficiency and optimized to be a multiple of the natural block size of the next-tier memory device.

[0107] In one embodiment, when the sensor logic 804 autonomously detects the availability of the network 101 (FIG. 1), the sensor logic 806 will trigger retiring buffered events in a first in, first out (FIFO) fashion. Where retrieving event from higher tier memory devices has a large penalty, the buffered event blocks can first be copied into the lowest penalty memory device forming the output queue 1111. In such an embodiment, once one event is successfully transmitted by the sensor body area communication device 805, the event data can be moved from a higher tier device, e.g., Tier N Memory 1103, and transmitted from the sensor 103 (FIG. 8) so that the event data can be permanently retired.

[0108] Thus, the sensor logic 804 defines and timestamps an event 1100. It is stored in the buffer 1106, and as new events are received from the sensor logic 804, the event 1100 is moved, i.e., copied to the second buffer 1105. As the resources are used up in Tier 1 Memory 1101, the event 1100 is moved to Tier 2 Memory 1107, and so on. When the sensor logic 804 decides to transfer data related to a particular event,

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the data is moved to the output queue **1111**, and then to the sensor body area communication device **805**.

[0109] Likewise, autonomous detection of the network's availability will trigger the oldest events to begin transmission and to begin effectively retiring these buffered events in a first in, first out (FIFO) fashion. In cases where retrieving events from higher tier memory devices has a large penalty, it is recognized that buffered event blocks can be first be copied into the lowest penalty memory device forming an output queue. Successful transmission of one block will trigger the fetch of the next oldest block and so on so that old events are systematically moved from higher tier devices and transmitted off-sensor so that they can be permanently retired.

[0110] Once the body area network **101** is operational for a period of time, all the event data in the higher tiers have been retired, events data can be queued directly to the output queue **1111** to maintain real-time transmission capability. If the network becomes inoperable again, event data can then be stored again in the tiered fashion described hereinabove.

[0111] In addition to event management, the system **100** performs contextual event data delivery. "Contextual event data delivery" refers to the function of recognizing and extracting data indicative of pertinent events in order to maximize scalability of the system **100** and minimize power consumption on the sensor **103-106**.

[0112] Notably, power consumption and other resources in the system **100** can be conserved by performing in-system real-time signal processing to extract features and events directly on the sensor node and avoiding expensive multiple transmissions for post data reduction. Also, the more data available, the better a signal can be faithfully reproduced. In many cases a sensor **103-106** monitors a given signal or parameter for extended periods of time only looking for a specific event occurrence which may happen infrequently. In such cases, it would be inefficient to transmit all raw data indicative of the event as the end user (not shown) may only be interested in inspection of a small window of time surrounding the event.

[0113] In one embodiment, the sensors **103-106** in the wireless network **101** perform a substantial level of on-sensor processing extracting only data indicative of particular events. Upon detection of an event by the sensor **103-106**, the sensor **103-106** autonomously transitions to raw data mode so as to provide maximum context for the event of interest. After some period of time the sensor **103-106** autonomously returns to reduced data (event only) mode.

[0114] In one embodiment, the sensor **103-106** includes a circular history buffer (not shown) which continuously stores raw event data for some finite period of time. In such an embodiment, when the sensor logic **804** detects an event, the sensor **103-106** transmits the circular history buffer, which represents context prior to the event of occurrence. In addition, the sensor logic **804** transmits raw event data following the event of interest. The amount of data transmitted after the event may vary. In this regard, it may be an amount defined by the number of bits to be transmitted or defined by a time period of collection.

[0115] FIG. 12 depicts one embodiment of the functionality of system **100** related to contextual event data delivery. As has been described throughout, controller **102** communicates with the sensor **103** via the body area network **101**. In the example in FIG. 12, the sensor **103** is employed in a health monitoring application wherein the sensor **103** continuously monitors heartbeats in an attempt to look for arrhythmic

events, heart-beat irregularities, or some other pertinent event. A treating physician may prefer to examine the raw heart waveforms immediately prior to and immediately following the arrhythmic event. The sensing device **806** (FIG. 8) receives regular heartbeats and the sensor logic **804** (FIG. 8) transfers data indicative of the heartbeats **1200**, **1201**, and so on, to the controller **102**. In one embodiment, the data indicative of the heartbeats **1200**, **1201**, and so on, can be sent, via the network **108** (FIG. 1) to the medical server **109** (FIG. 1) where a physician or caregiver may inspect further.

[0116] When the sensing device **806** detects an arrhythmic event, the sensor logic **804** transmits data indicative of the arrhythmic event **1202** to the controller **102**. The sensor logic **804** then transmits raw data **1203** continuously to the controller **102** so that the user can review the actual raw data that is being obtained by the sensing device **806**.

[0117] FIG. 13 is a block diagram depicting an exemplary software architecture and functionality for implementing the example depicted in FIG. 12. The sensor logic **804** receives raw data in response to an interrupt service routine (ISR). The sensor logic **804** stores the data in a history buffer **1300**. Exemplary history buffers include a ring buffer (not shown) or a first in first out (FIFO) queue (not shown) with an overflow policy that retires old samples rather than new samples.

[0118] The history buffer **1300** stores the previous N samples of raw data where N represents the maximum number of samples of raw data that can be stored in the buffer **1300**. The raw data samples are also provided as input to application-specific sensor logic **804**, and the sensor logic **804** employs event detection algorithms **1301** for detecting a pre-defined event, for example an arrhythmic occurrence if the sensor logic **804** is designed to process heartbeat signals. In addition, the sensor logic **804** employs a transmit algorithm **1302** for retrieving event data from the history buffer **1300** and transmitting it to the controller **102**.

[0119] Upon detection of an event by the event detection algorithm **1301**, the transmit algorithm is signaled to begin transmission of M raw samples. M can be set by the needs of the application, but typically $M=2N$, so that upon event detection N preceding samples, where N is the depth of the existing history buffer prior to event detection, and the next N following samples will be transmitted thus providing balanced context of the specific event.

[0120] FIG. 14 depicts another embodiment of the present disclosure related to context event data delivery. As has been described throughout, controller **102** communicates with the sensor **103** via the body area network **101**. In the example in FIG. 14, the sensor **103** is employed in a health monitoring application wherein the sensor **103** continuously monitors heartbeats in an attempt to look for arrhythmic events, heart-beat irregularities, or some other pertinent event similar to the description with reference to FIG. 12.

[0121] The sensing device **806** (FIG. 8) receives regular heartbeats and the sensor logic **804** (FIG. 8) transfers data indicative of the heartbeats **1400**, **1401**, and so on, to the controller **102**. When the sensing device **806** detects an arrhythmic event, the sensor logic **804** transmits data indicative of the arrhythmic event **1402** to the controller **102**. In response, the control logic **204** transmits a message **1404** requesting raw data mode.

[0122] In response to the request **1404**, the sensor logic **804** then transmits raw data **1403** to the controller **102** so that the user can review the actual raw data that is being obtained by the sensing device **806**. The sensor logic **804** continues to

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transmit the raw data **1403** until the control logic **204** transmits a message **1405** requesting that the raw data mode be terminated.

[0123] FIG. 15 is a flowchart depicting exemplary architecture and functionality of the control logic **204** (FIG. 2) and its calibration functionality. In step **1600**, the control logic **204** calculates a calibration value based upon an initial state of a sensor **103-106**. In step **1601**, the control logic **204** stores the value in memory **201** (FIG. 2).

[0124] During operation, the control logic **204** obtains a reading from a sensor **103-106**, as indicated in step **1602**. In step **1603**, the control logic **204** modifies the reading based upon the calibration value.

[0125] This invention may be provided in other specific forms and embodiments without departing from the essential characteristics as described herein. The embodiments described above are to be considered in all aspects as illustrative only and not restrictive in any manner.

[0126] As described above and shown in the associated drawings, the present invention comprises wireless sensor network and method for using the same. While particular embodiments of the invention have been described, it will be understood, however, that the invention is not limited thereto, since modifications may be made by those skilled in the art, particularly in light of the foregoing teachings. It is, therefore, contemplated by the appended claims to cover any such modifications that incorporate those features or those improvements that embody the spirit and scope of the present invention.

1. A system, comprising:
at least one sensor;
a controller communicatively coupled to the sensor via a network; and
logic configured to calculate a calibration value based upon an initial state of the sensor and stored the calibration value in memory.
2. The system of claim 2, wherein the logic is further configured to obtain at least one reading from the sensor and modify the reading based upon the calibration value.
3. The system of claim 1, wherein the initial state of the sensor is based upon a location of the sensor on a body.
4. The system of claim 1, wherein the initial state of the sensor is based upon a measure of the sensor's performance.
5. The system of claim 1, wherein the initial state of the sensor is based upon a measure of the performance of a battery powering the sensor.
6. The system of claim 1, wherein the initial state of the sensor is based upon a measure of the temperature in an operating environment of the sensor.
7. The system of claim 1, wherein the initial state of the sensor is based upon a measure of the humidity in an operating environment of the sensor.

8. The system of claim 1, wherein the sensor is coupled to a body.

9. The system of claim 1, wherein the logic is further configured to calculate an affect related to an operation-changing factor and generate a function representing the affect of the factor on the sensor.

10. The system of claim 9, wherein the logic is further configured to obtain a reading from the sensor and apply the function to the reading.

11. A method, comprising the steps of:
coupling a sensor to a body;
communicatively coupling a controller to the sensor;
calculating a calibration value based upon an initial state of the sensor.

12. The method of claim 11, further comprising the step of obtaining data indicative of a reading from the sensor.

13. The method of claim 12, further comprising the step of modifying the data based upon the calibration value.

14. The method of claim 11, wherein the calculating step further comprises the step of calculating the initial state of the sensor based upon a location of the sensor on a body.

15. The system of claim 11, wherein the calculating step further comprises the step of calculating the initial state of the sensor based upon a measure of the sensor's performance.

16. The method of claim 11, wherein the calculating step further comprising the step of calculating the initial state of the sensor based upon a measure of the performance of a battery powering the sensor.

17. The method of claim 11, wherein the calculating step further comprising the step of calculating the initial state of the sensor based upon a measure of the temperature in an operating environment of the sensor.

18. The method of claim 11, wherein the calculating step further comprising the step of calculating the initial state of the sensor based upon a measure of the humidity in an operating environment of the sensor.

19. The method of claim 11, further comprising the step of calculating an affect related to an operation-changing factor and generate a function representing the affect of the factor on the sensor.

20. The method of claim 19, further comprising the steps of:

obtaining a reading from the sensor; and
applying the function to the reading.

21. A system, comprising:
at least one sensor;
a controller communicatively coupled to the sensor; and
means for calculating a calibration value based upon an initial state of the sensor.

* * * * *

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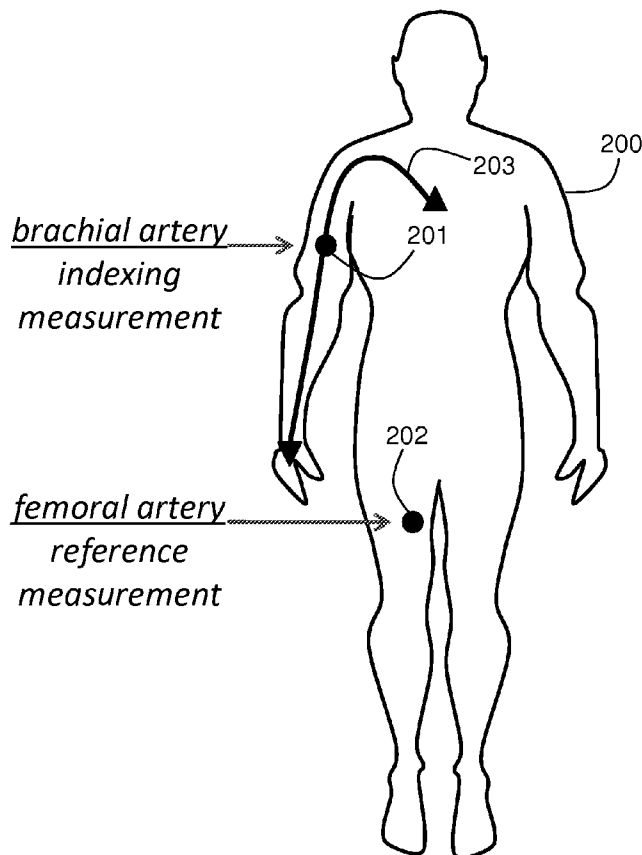
GZJ DKV'35''



US 20100160798A1

(19) **United States**(12) **Patent Application Publication**
BANET et al.(10) **Pub. No.: US 2010/0160798 A1**(43) **Pub. Date: Jun. 24, 2010**(54) **BODY-WORN SYSTEM FOR MEASURING
CONTINUOUS NON-INVASIVE BLOOD
PRESSURE (CNIBP)**(60) Provisional application No. 60/943,464, filed on Jun.
12, 2007, provisional application No. 60/983,198,
filed on Oct. 28, 2007.(75) Inventors: **Matt BANET**, Kihei, HI (US);
Marshal DHILLON, San Diego,
CA (US); **Devin McCOMBIE**, San
Diego, CA (US)**Publication Classification**(51) **Int. Cl.**
A61B 5/022 (2006.01)(52) **U.S. Cl.** **600/490**Correspondence Address:
BioTechnology Law Group
12707 High Bluff Drive
Suite 200
San Diego, CA 92130-2037 (US)(57) **ABSTRACT**

The present invention provides a technique for continuous measurement of blood pressure based on pulse transit time and which does not require any external calibration. This technique, referred to herein as the 'Composite Method', is carried out with a body-worn monitor that measures blood pressure and other vital signs, and wirelessly transmits them to a remote monitor. A network of body-worn sensors, typically placed on the patient's right arm and chest, connect to the body-worn monitor and measure time-dependent ECG, PPG, accelerometer, and pressure waveforms. The disposable sensors can include a cuff that features an inflatable bladder coupled to a pressure sensor, three or more electrical sensors (e.g. electrodes), three or more accelerometers, a temperature sensor, and an optical sensor (e.g., a light source and photodiode) attached to the patient's thumb.

(73) Assignee: **SOTERA WIRELESS, INC.**, San
Diego, CA (US)(21) Appl. No.: **12/650,370**(22) Filed: **Dec. 30, 2009****Related U.S. Application Data**(63) Continuation-in-part of application No. 12/138,194,
filed on Jun. 12, 2008.

Pressure-Free Measurement

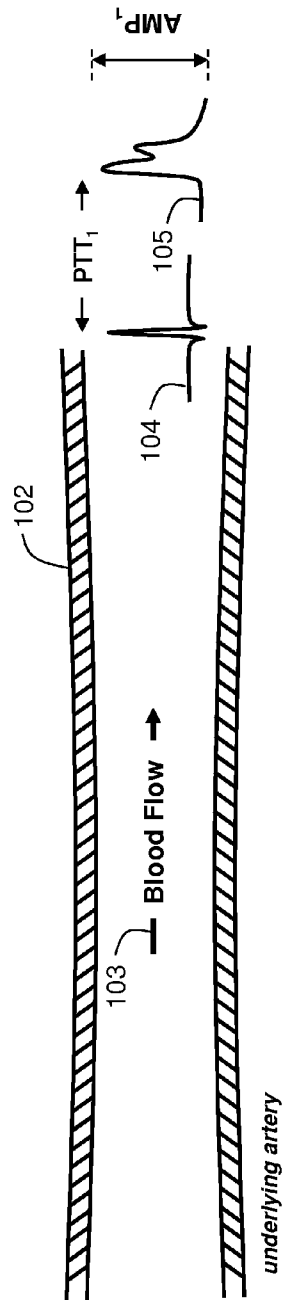


Fig. 1A

Pressure-Dependent Measurement

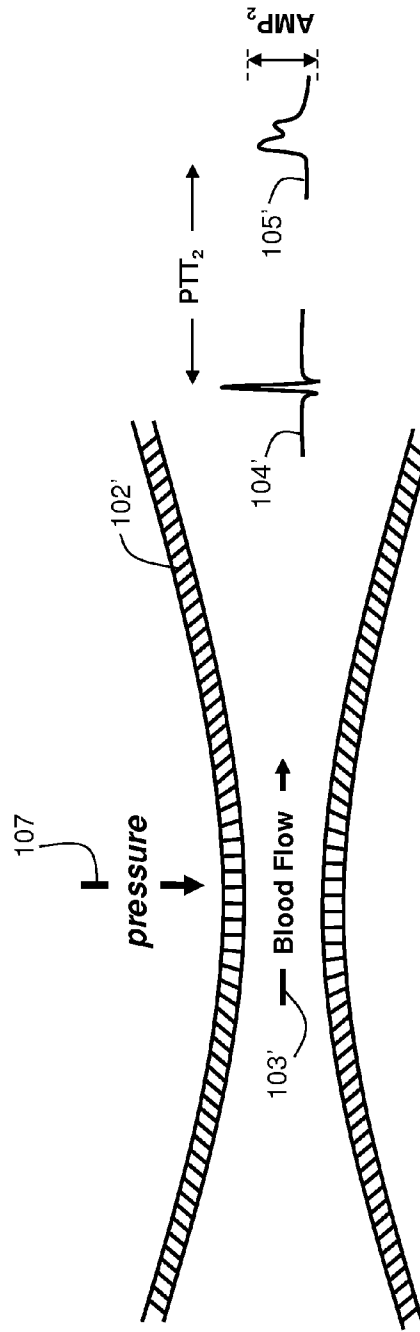
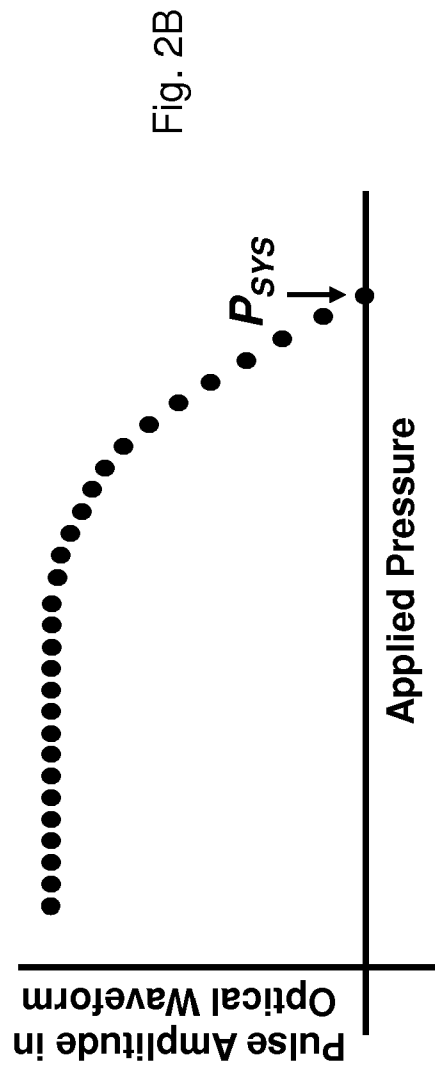
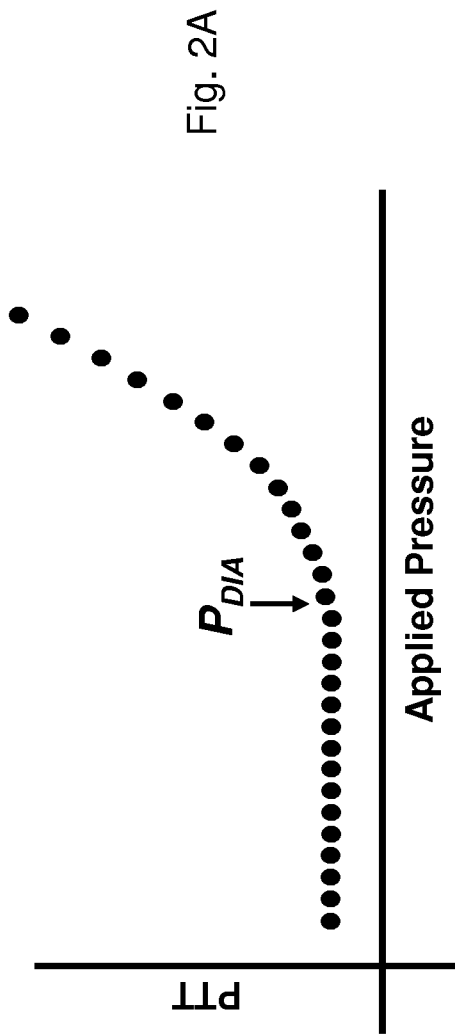


Fig. 1B



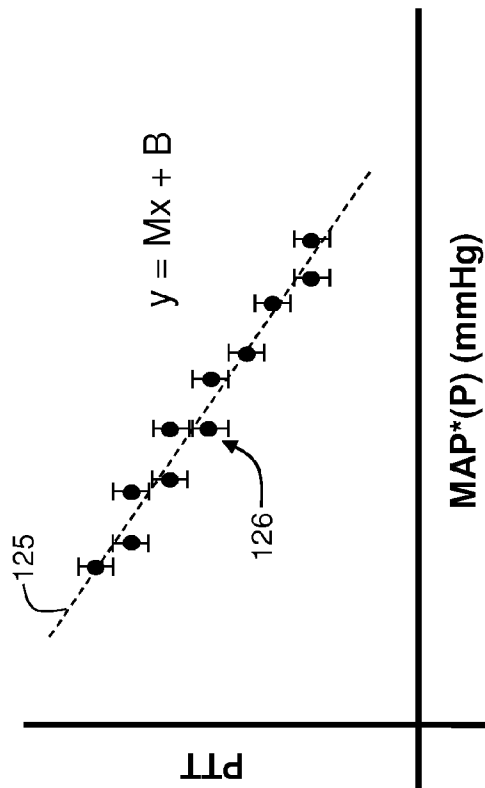


Fig. 3A

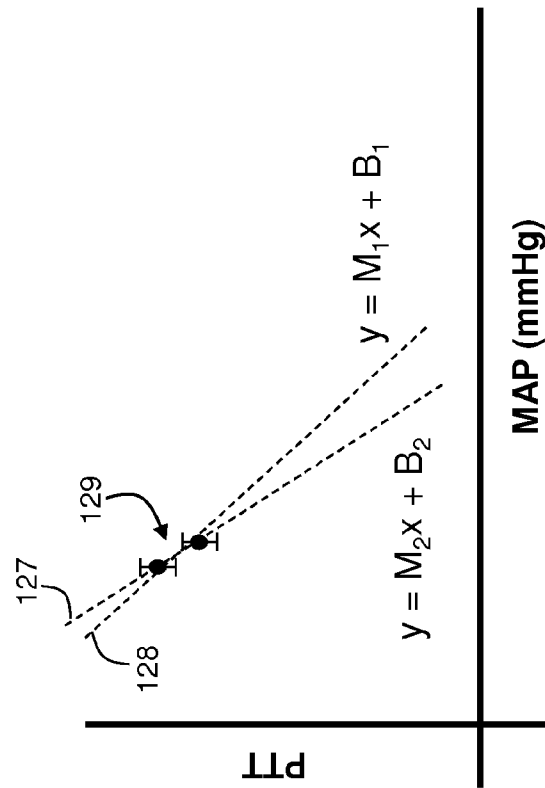


Fig. 3B

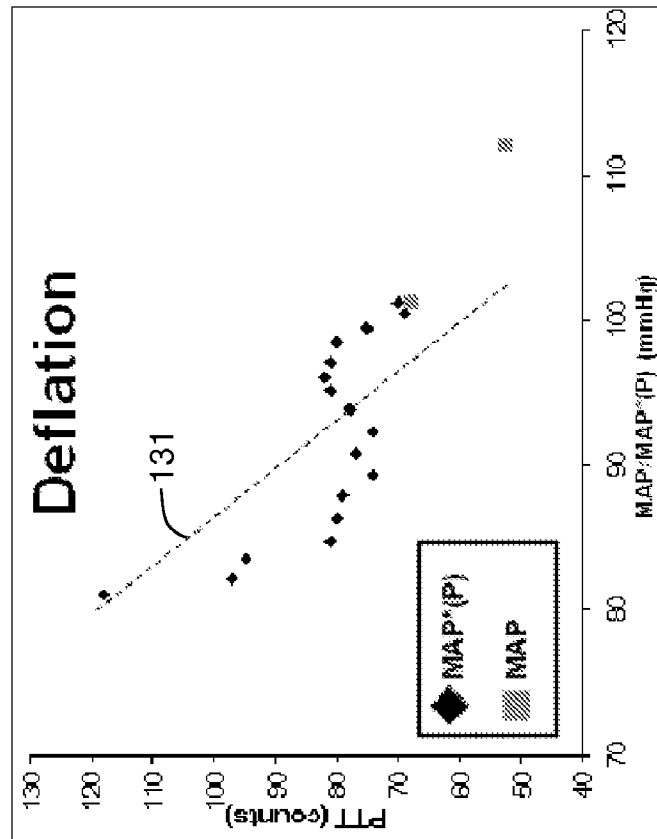


Fig. 4B

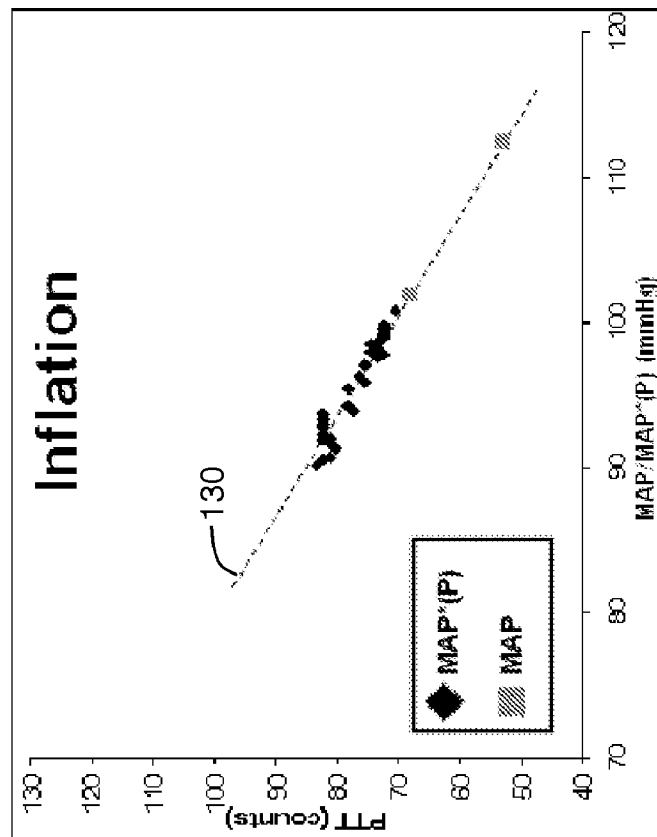
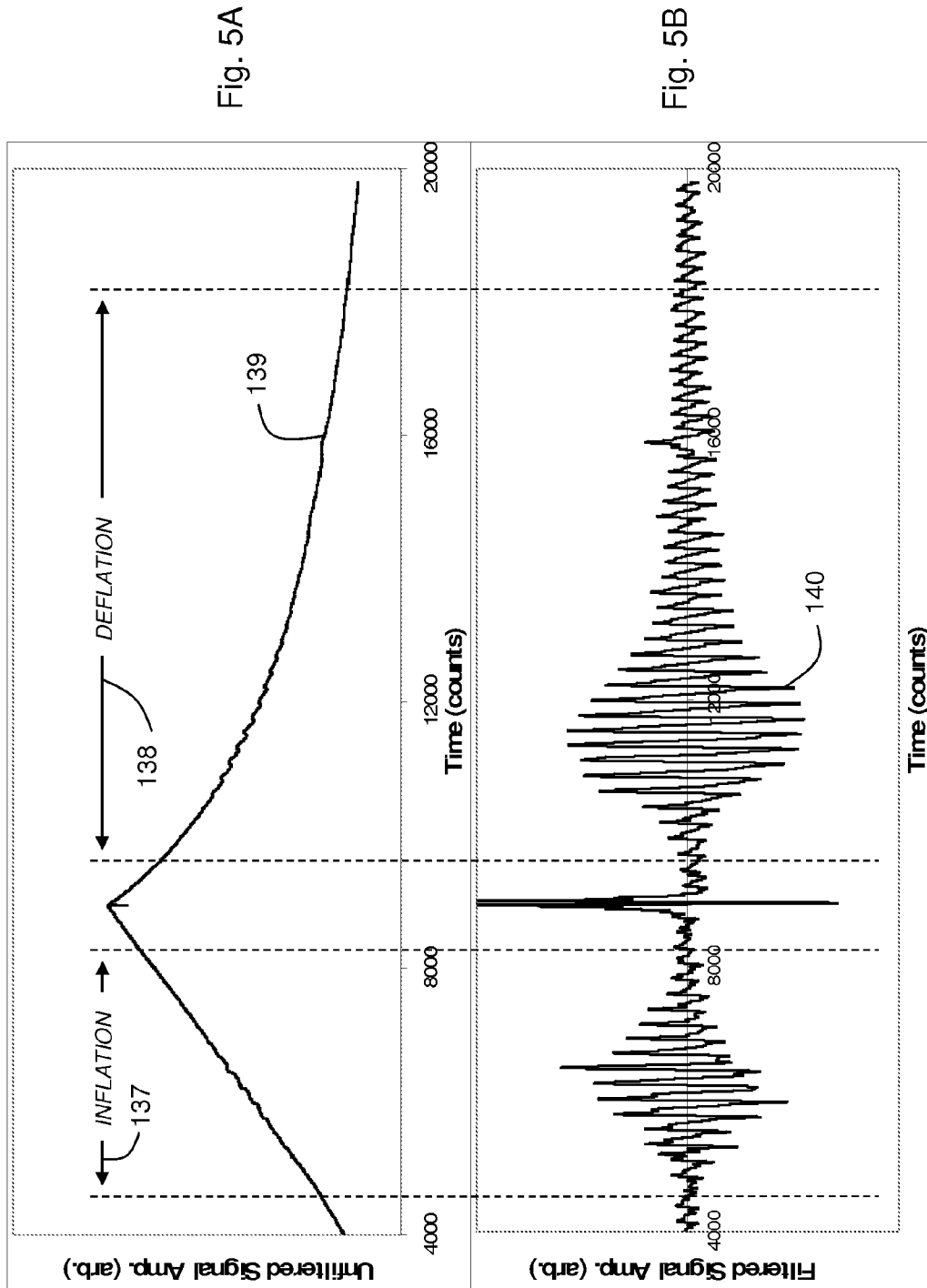


Fig. 4A



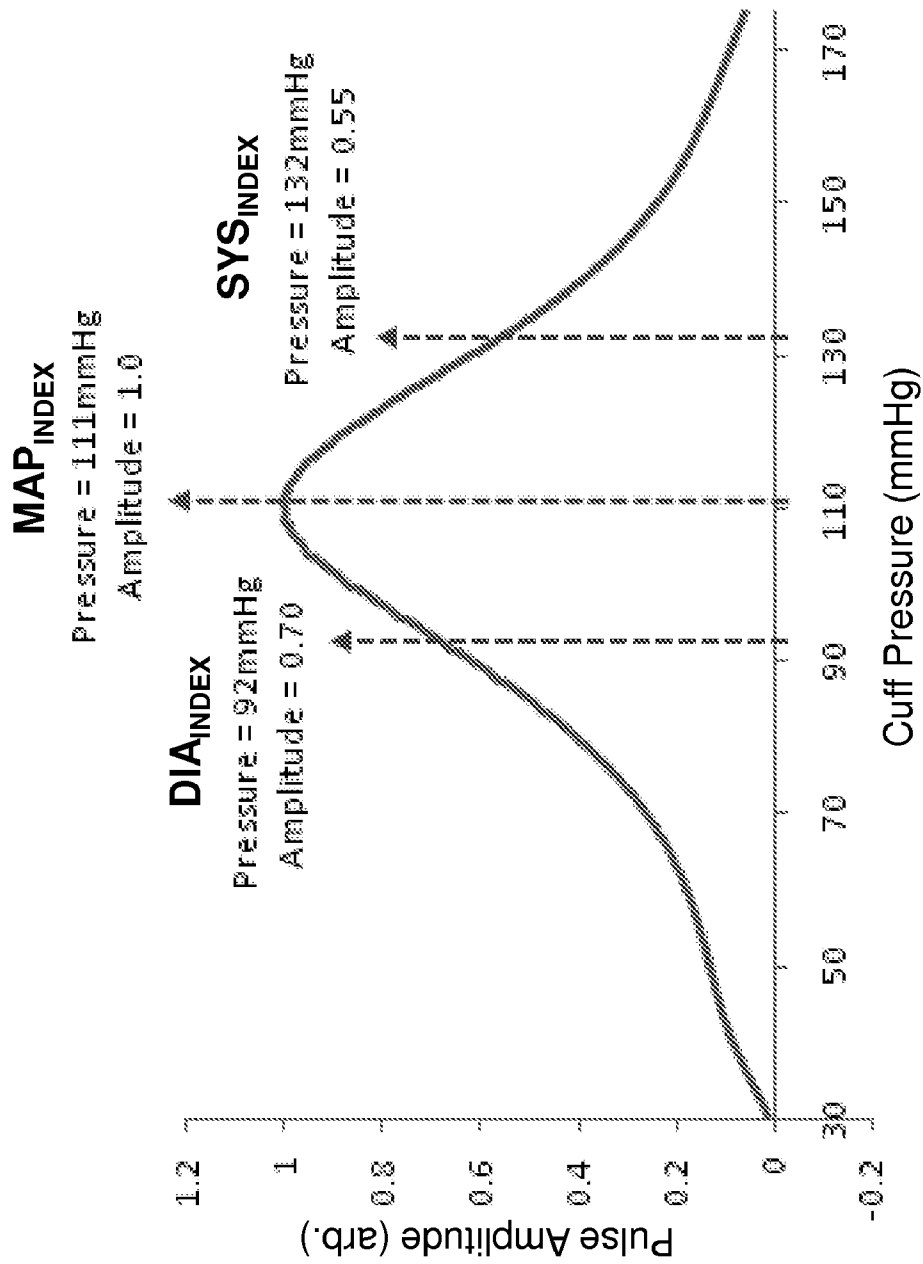


Fig. 6

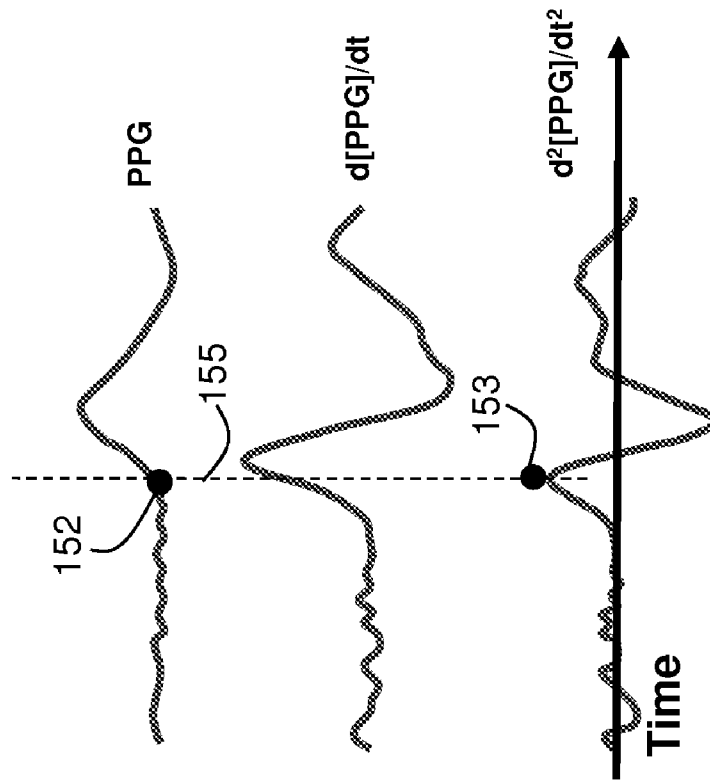


Fig. 7B

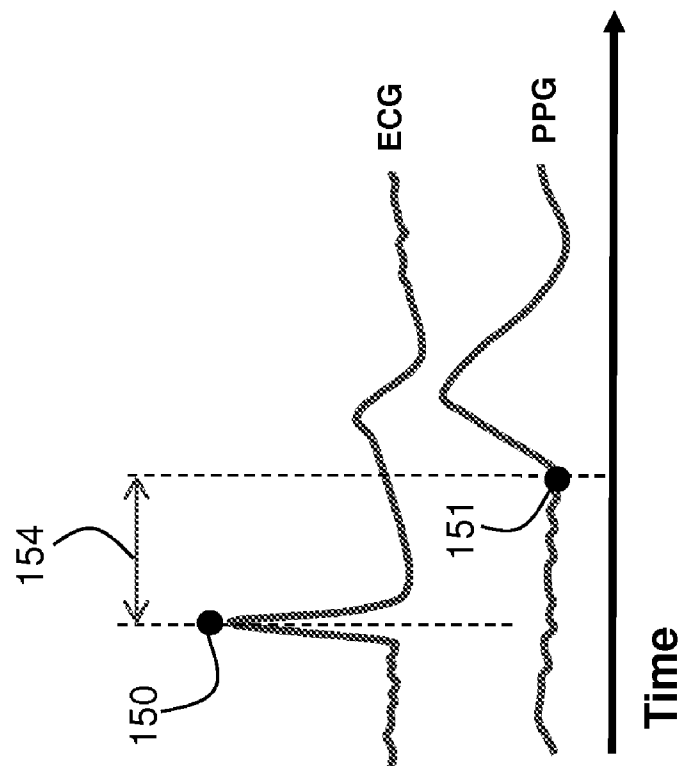


Fig. 7A

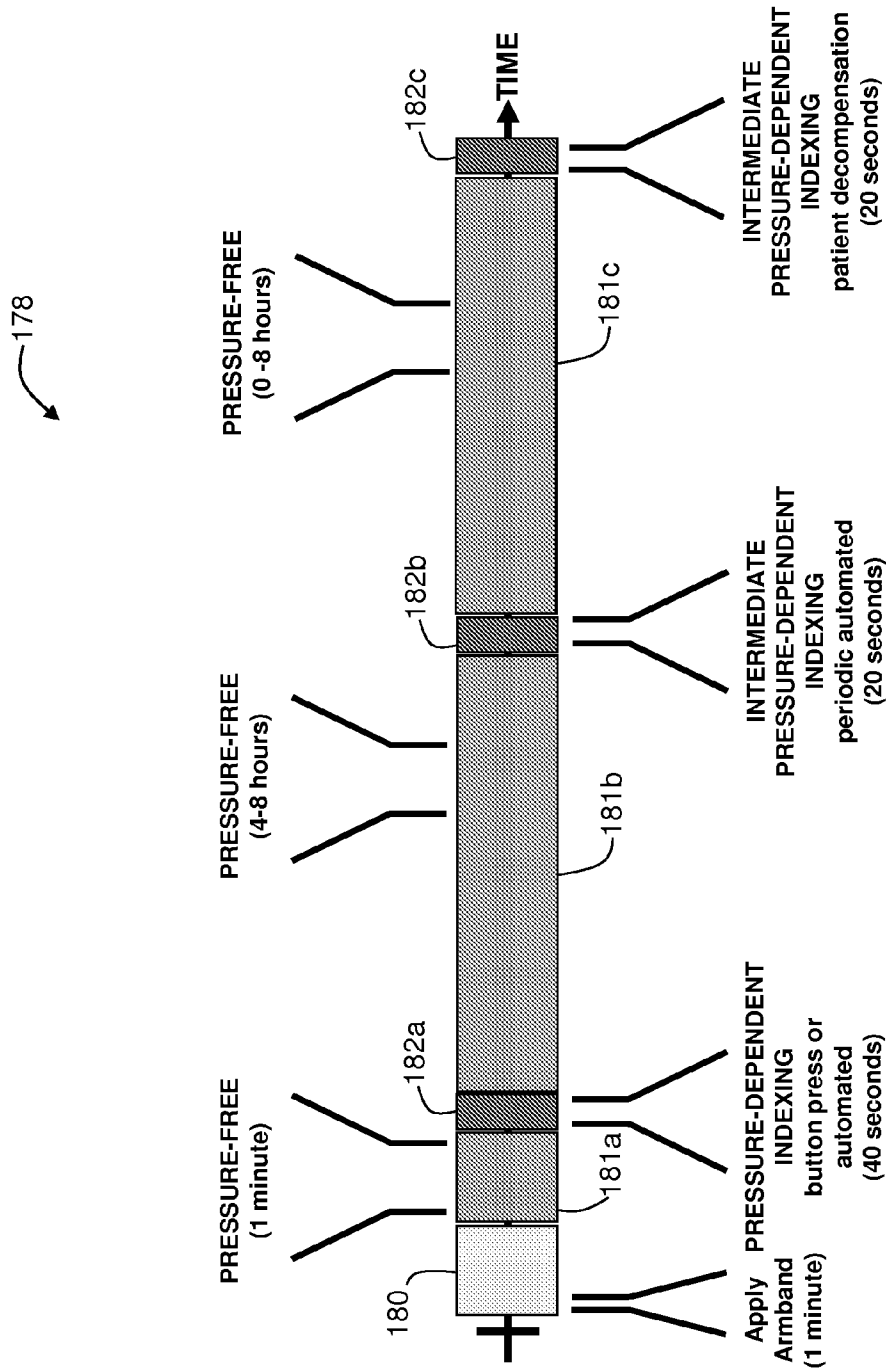


Fig. 8

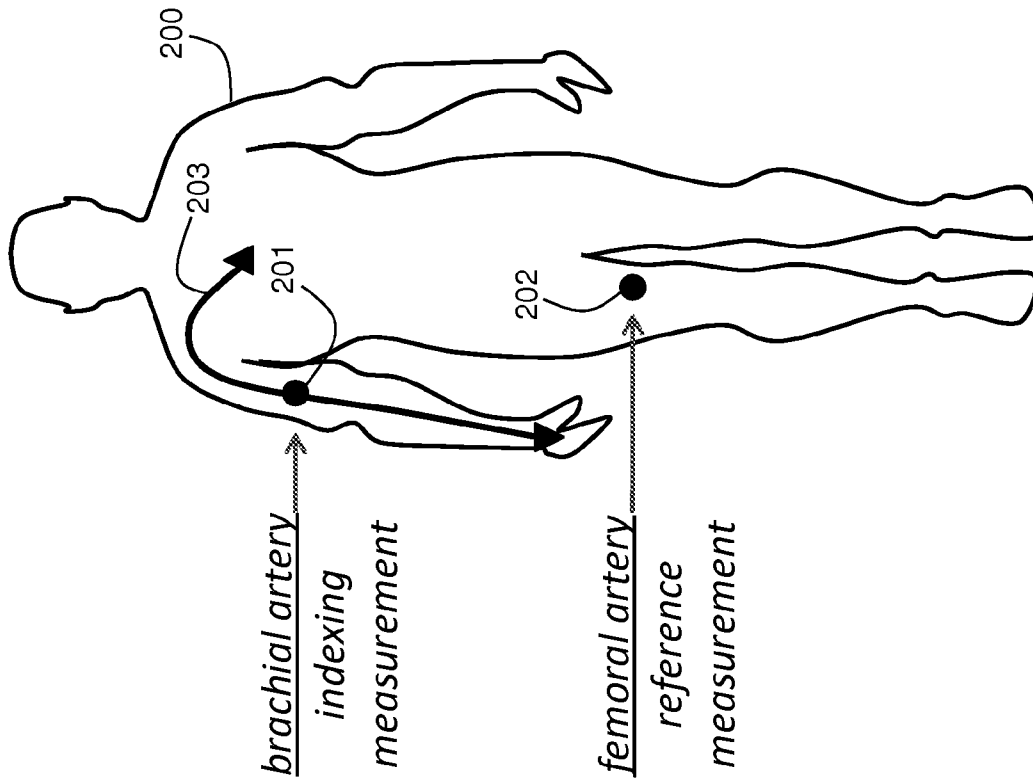


Fig. 9

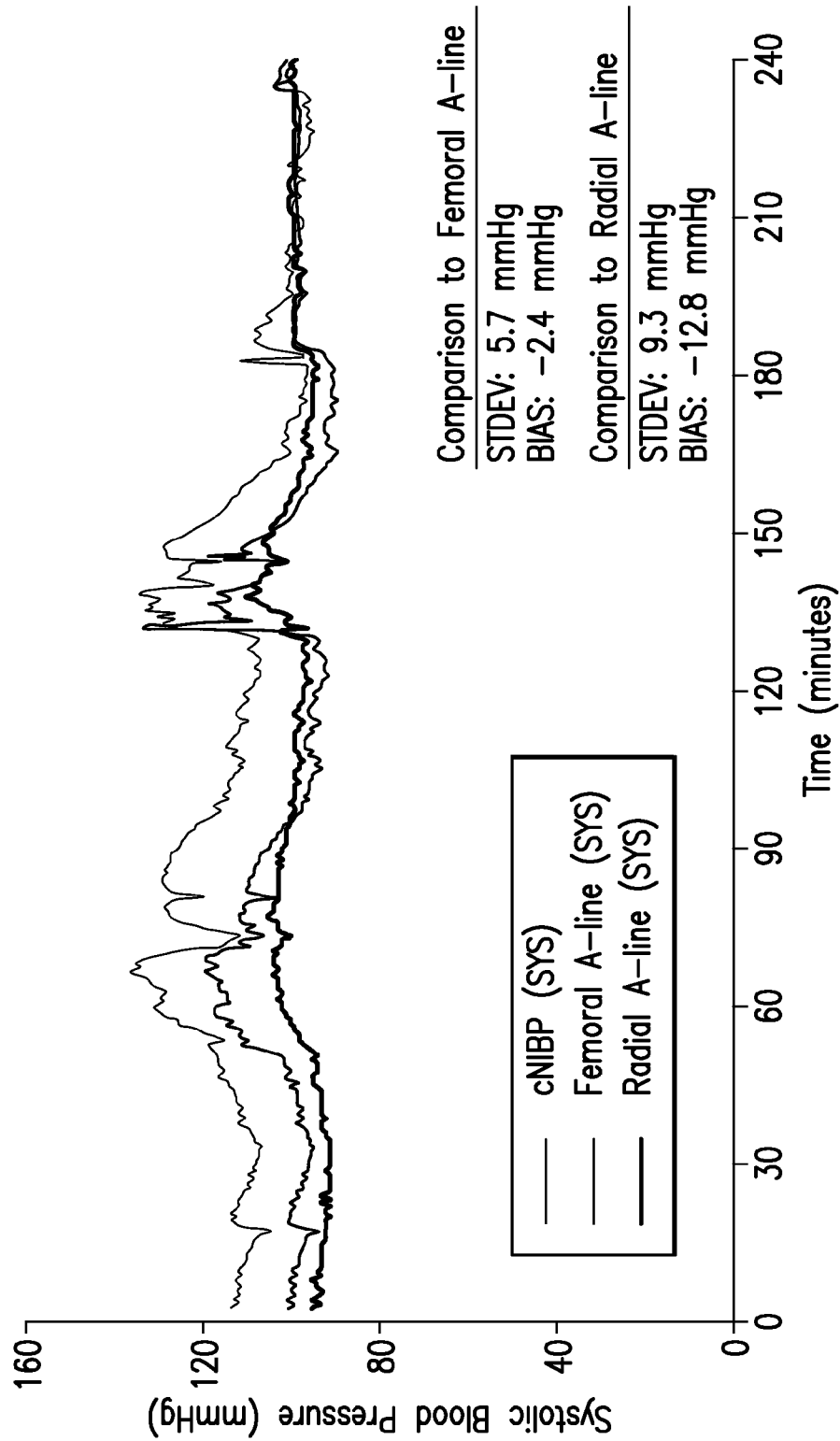
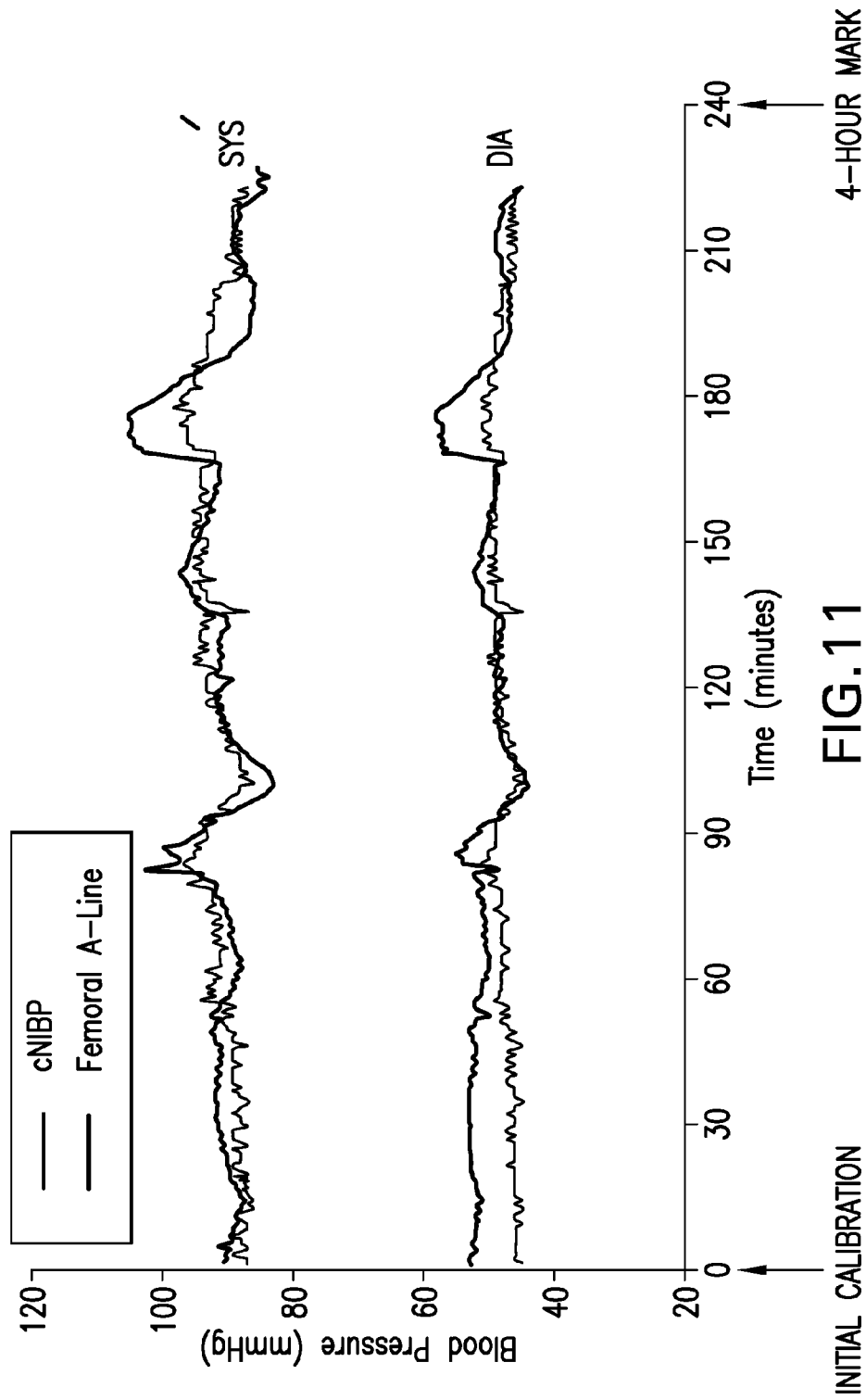


FIG.10



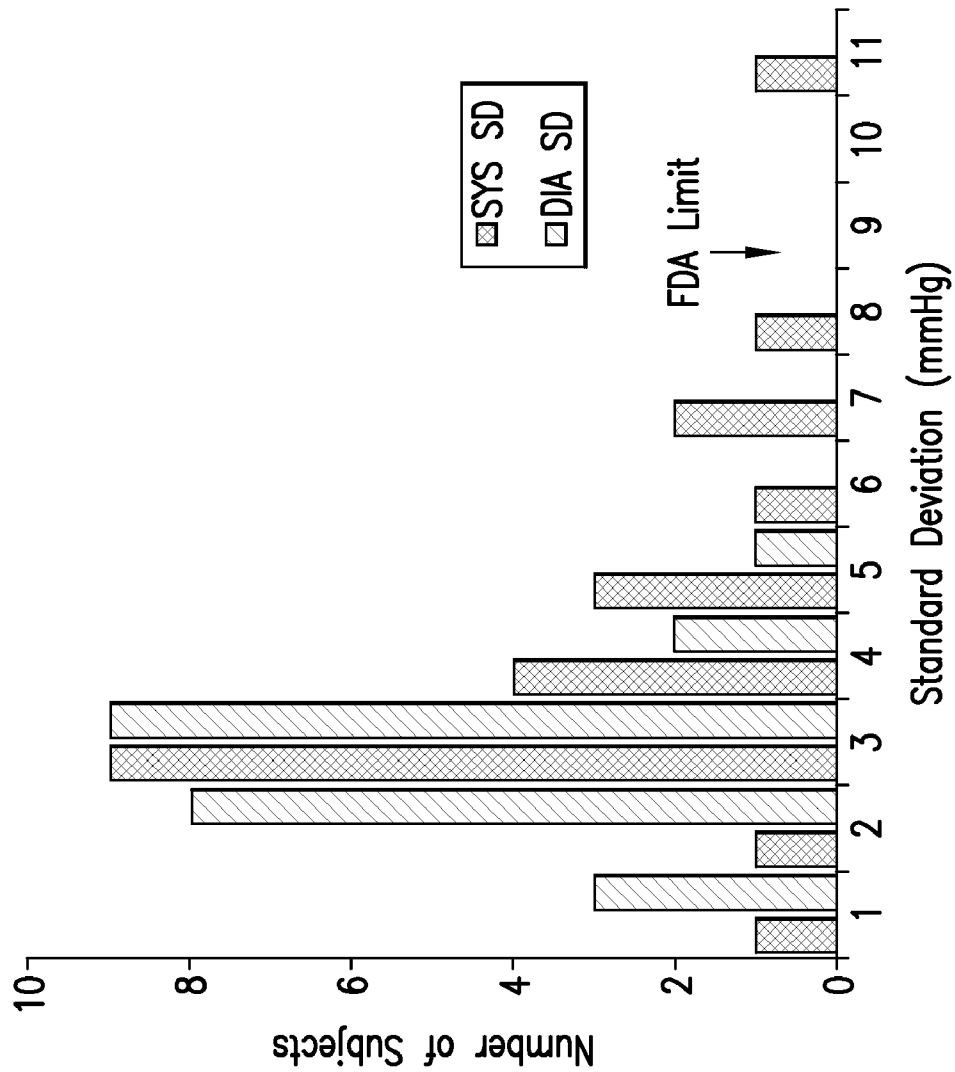


FIG. 12

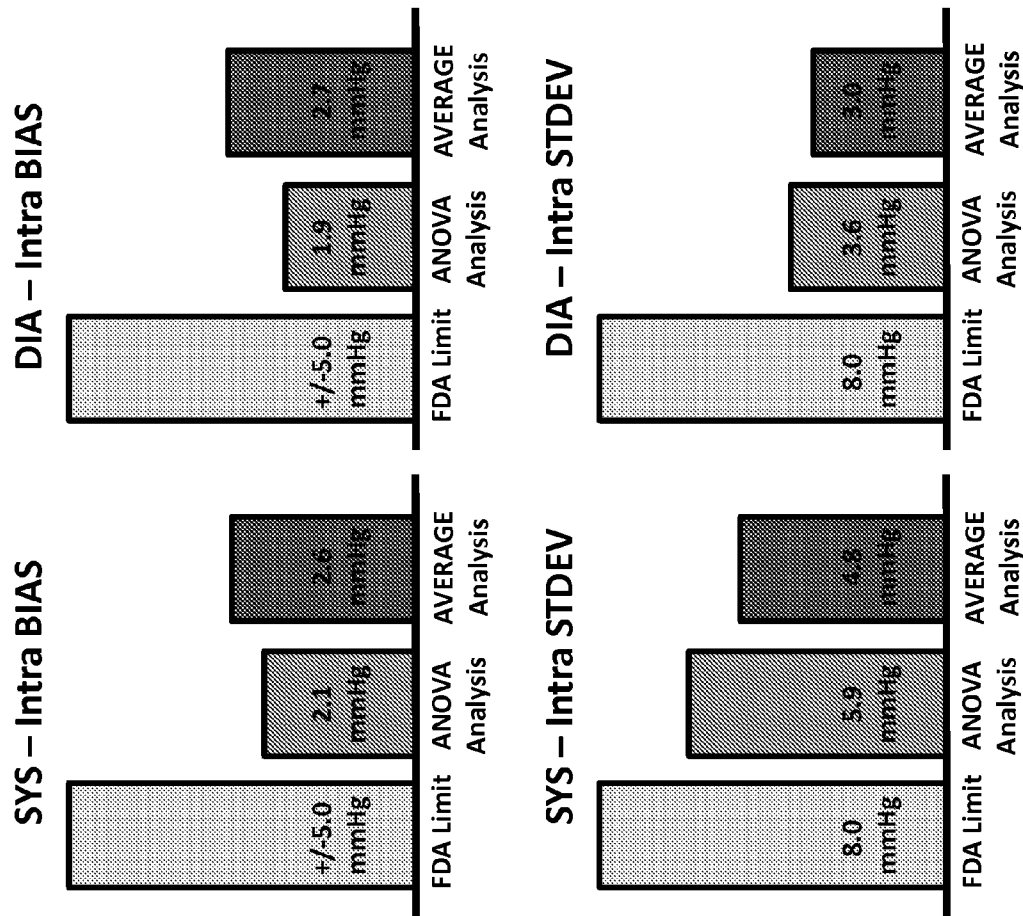
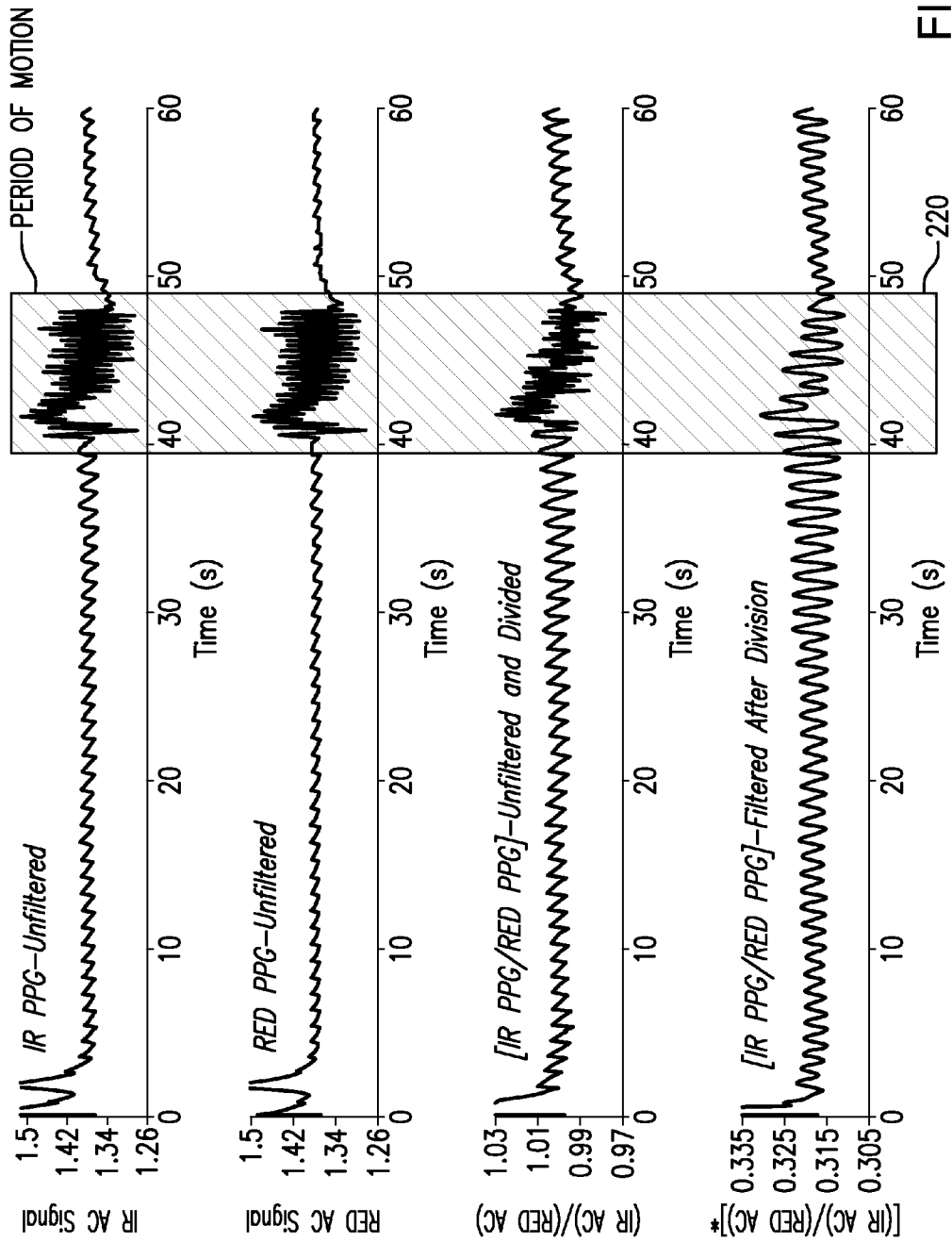


Fig. 13

Calibration Period	SYS DRIFT	DIA DRIFT
4 Hours (N = 22)	-0.07 mmHg/hour P = 0.03	-0.01 mmHg/hour not significant
8 Hours (N = 6)	-0.4 mmHg/hour P = 0.004	-0.3 mmHg/hour P = 0.0002

Fig. 14



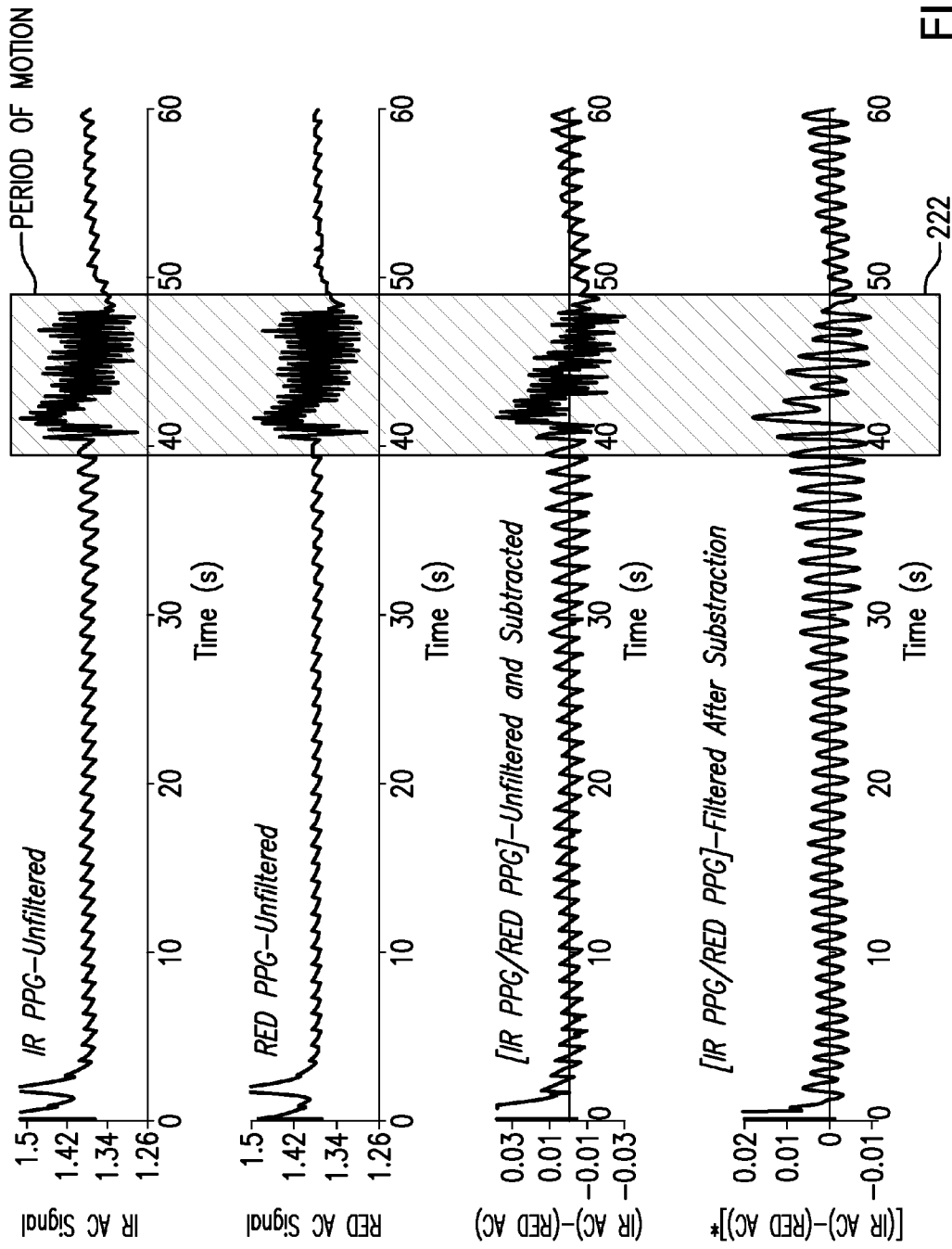


FIG.16

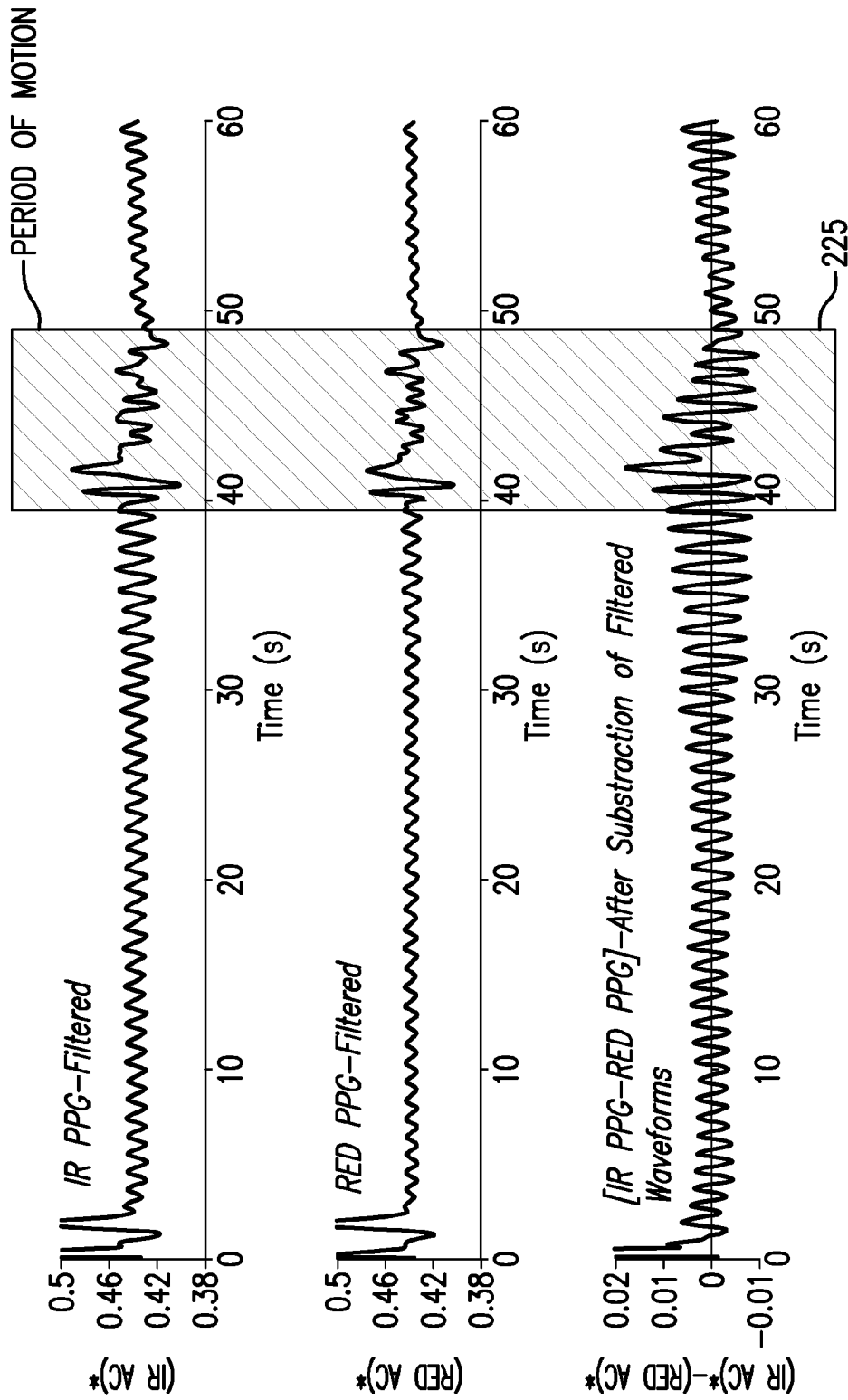


FIG. 17

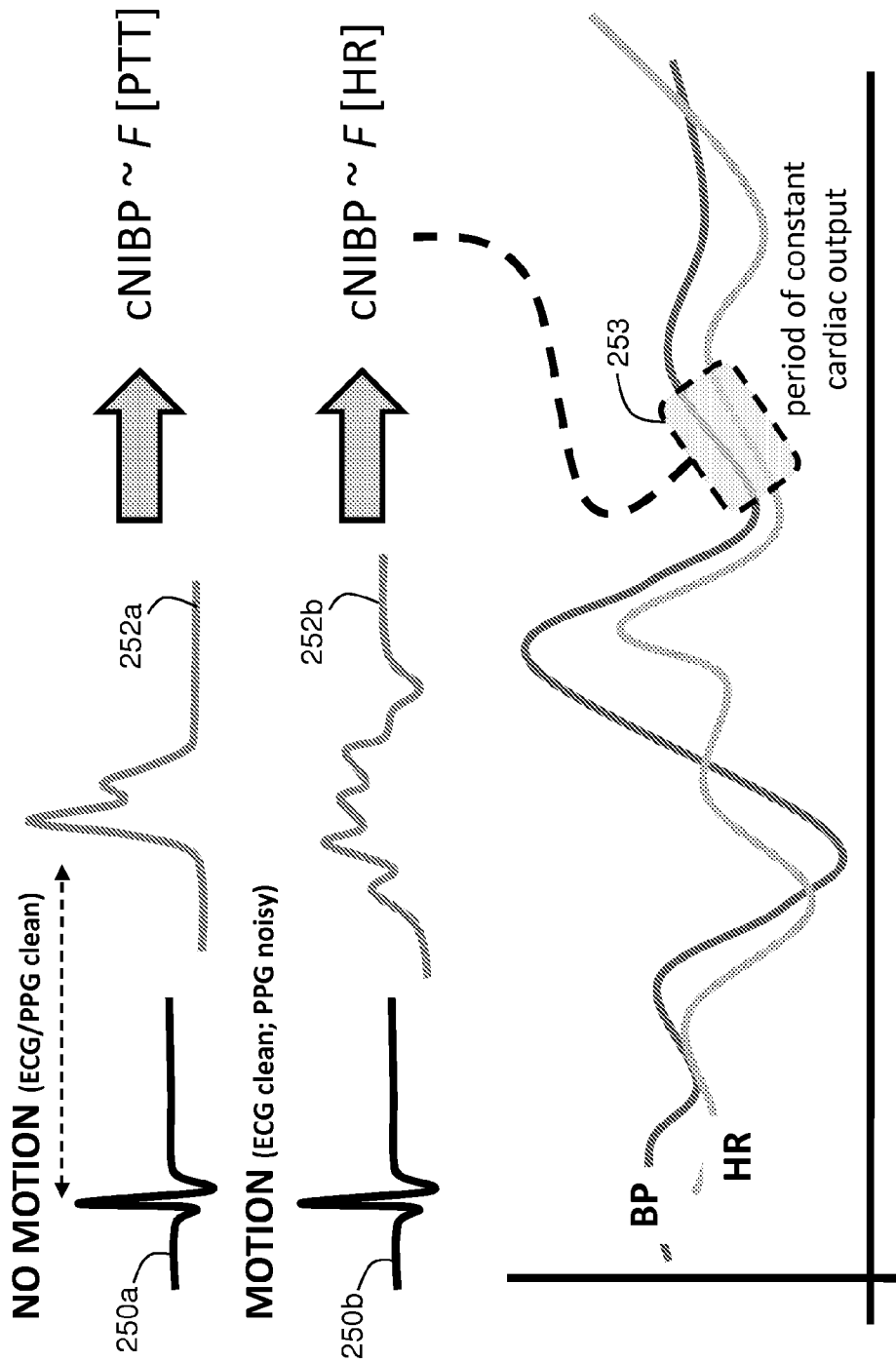


Fig. 18

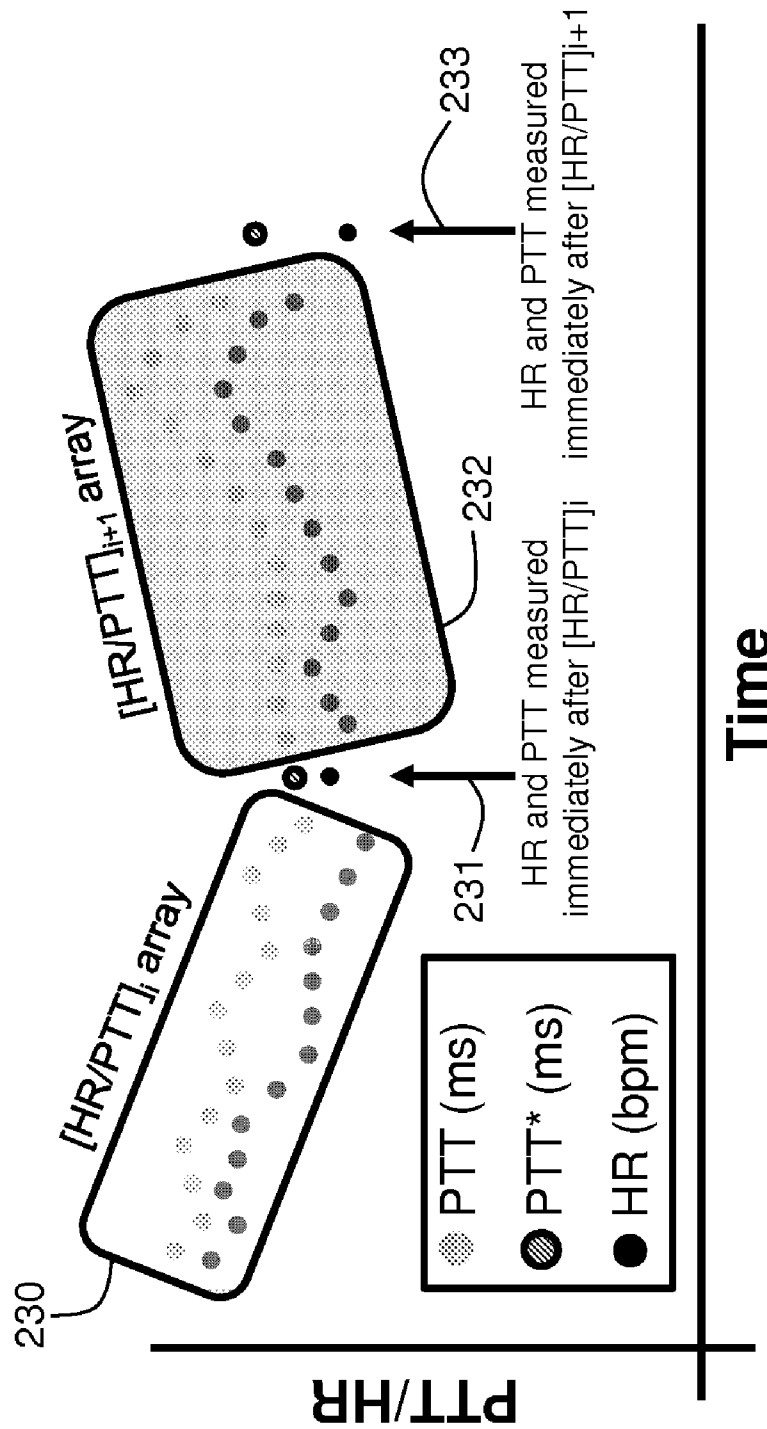


Fig. 19

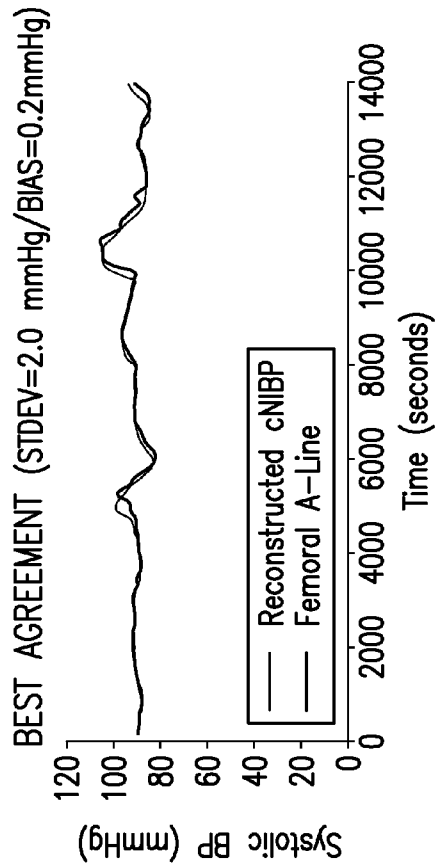


FIG.20A

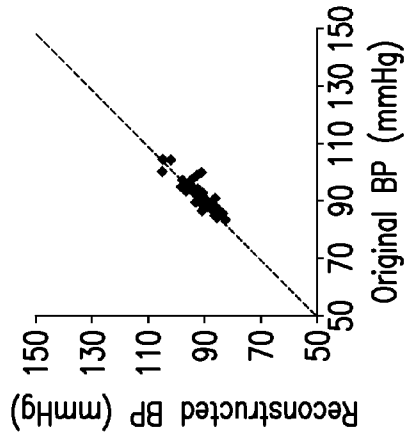


FIG.20B

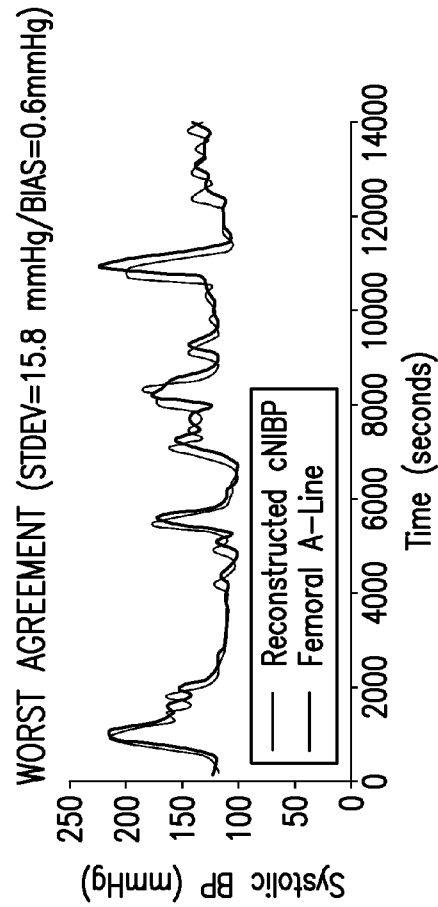


FIG.21A

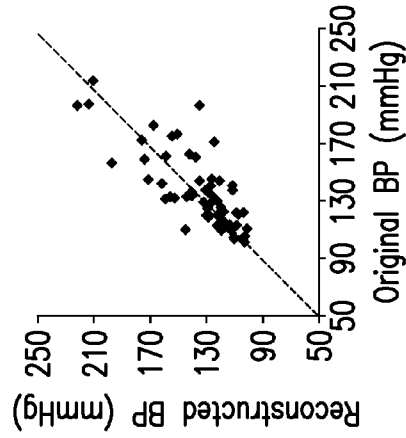


FIG.21B

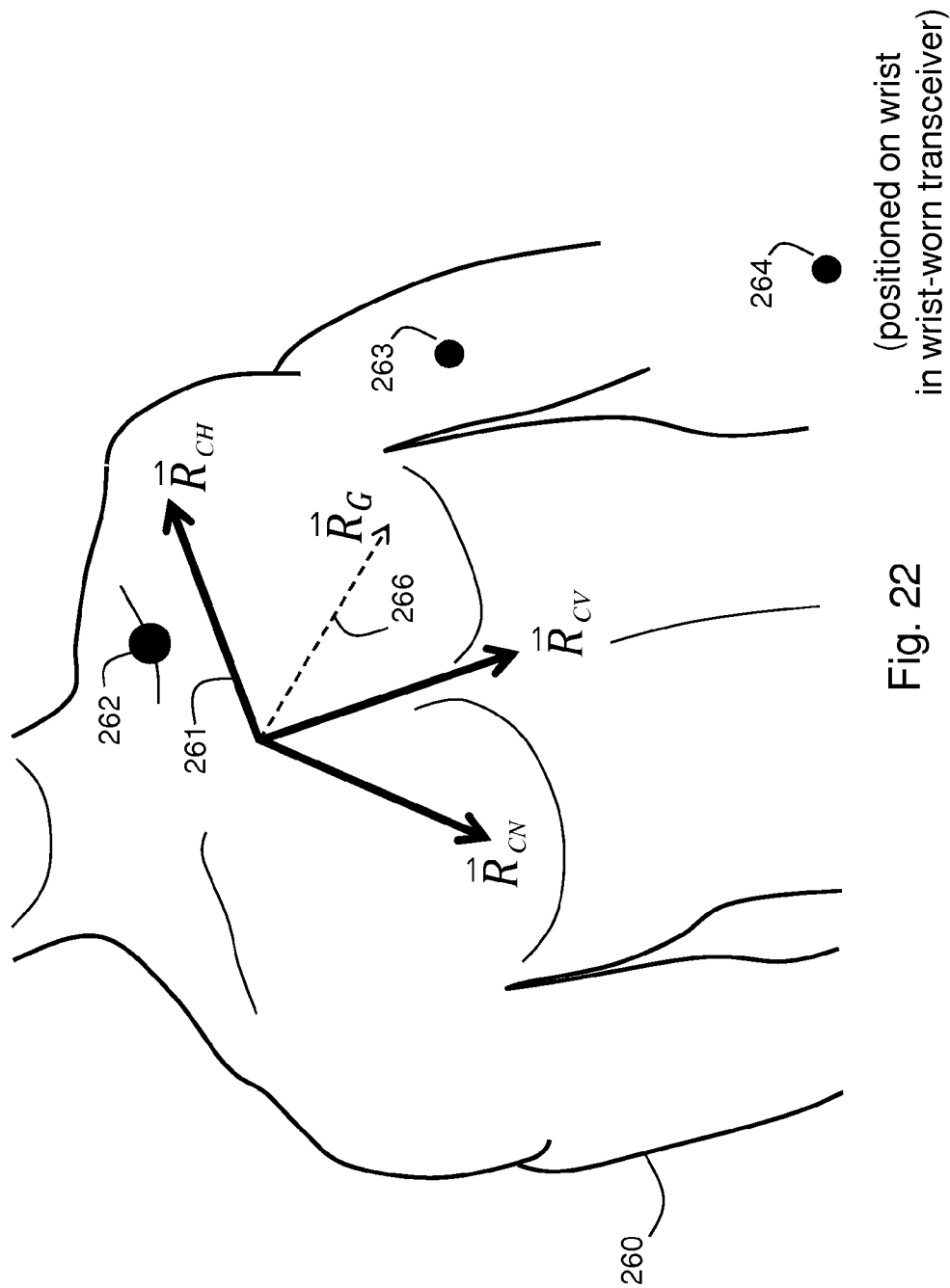
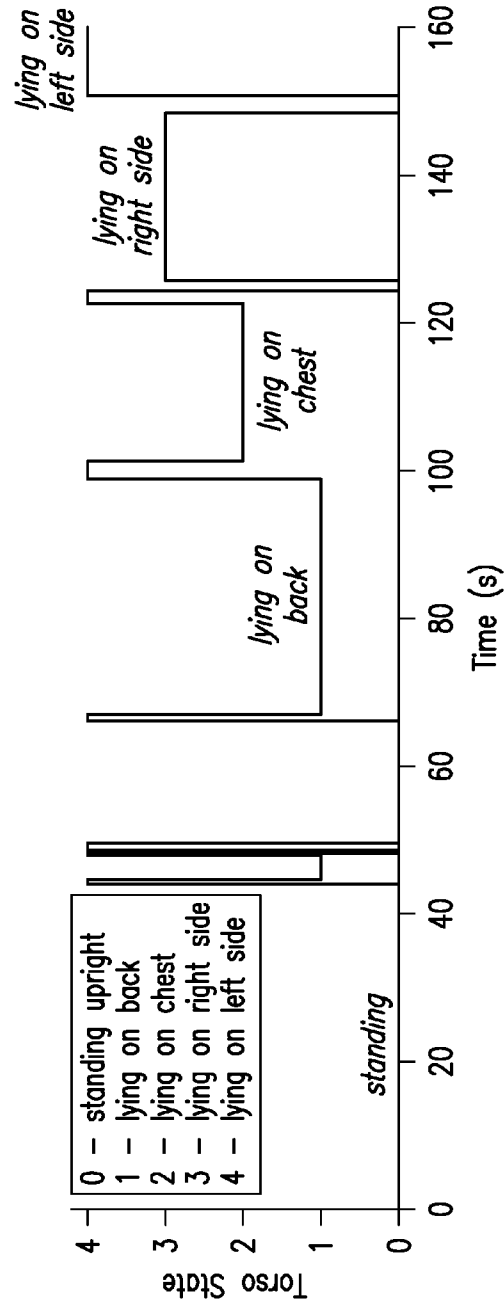
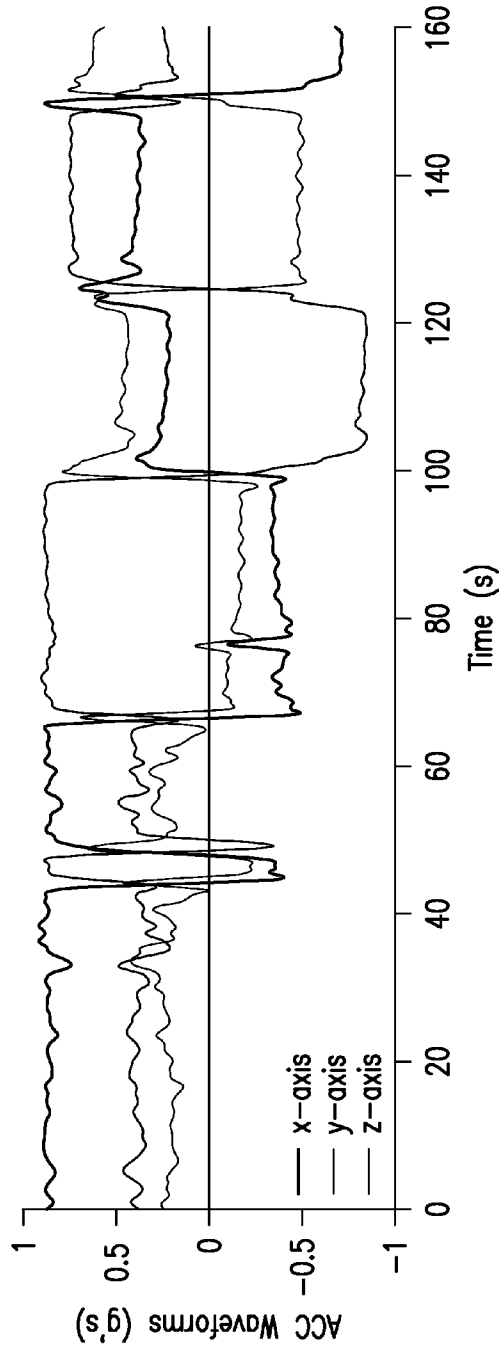


Fig. 22



Configuration for Indexing cNIBP Measurement
(first ~60 seconds)

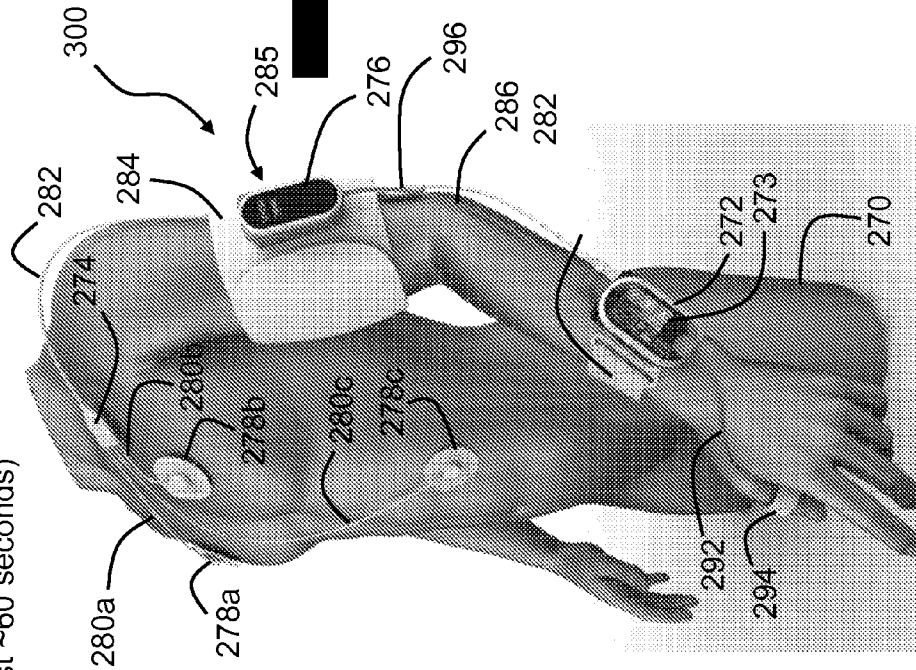


FIG. 24A

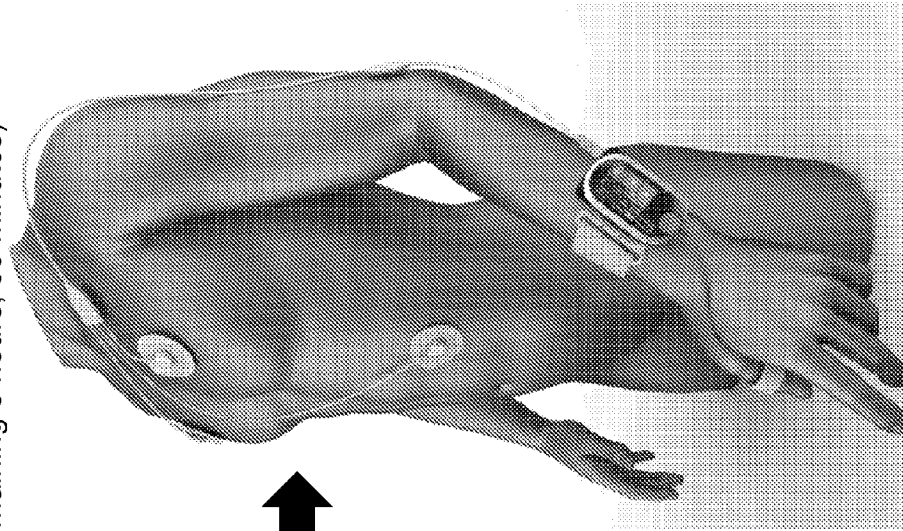


FIG. 24B

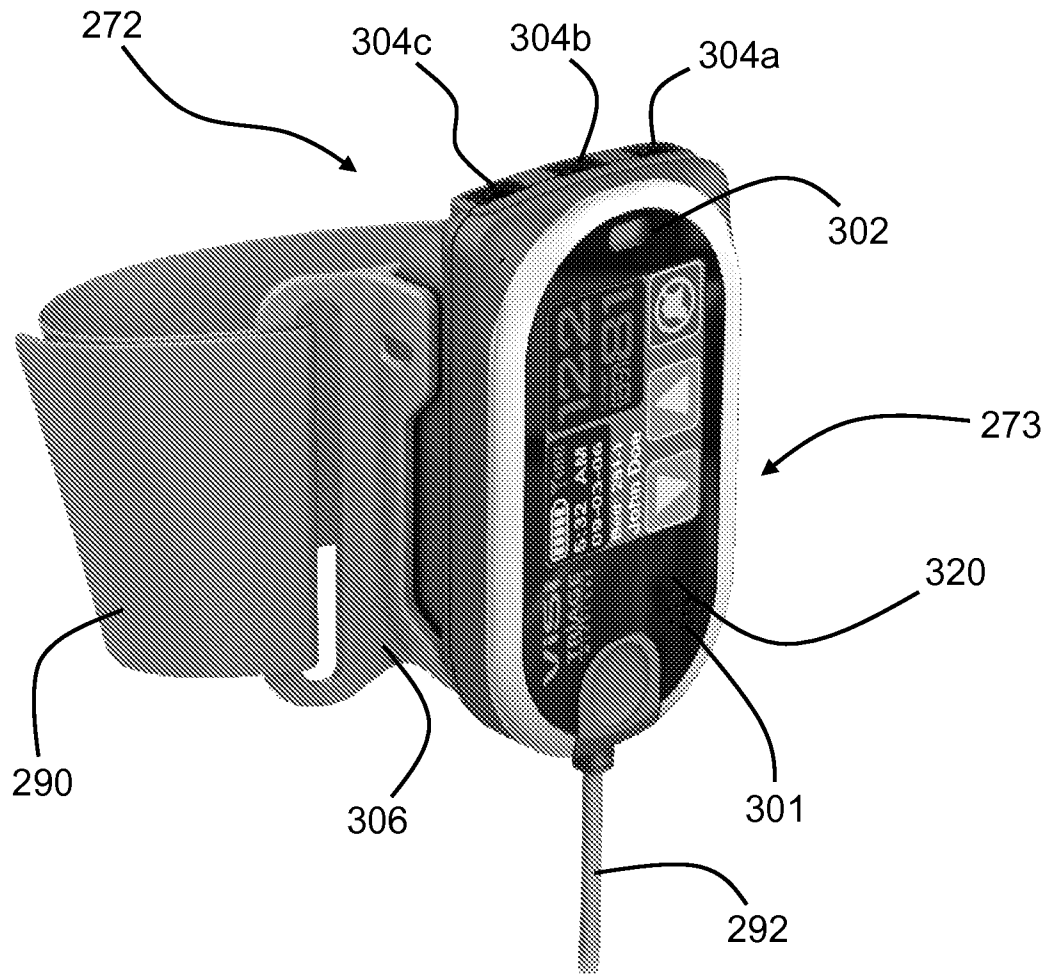


FIG. 25

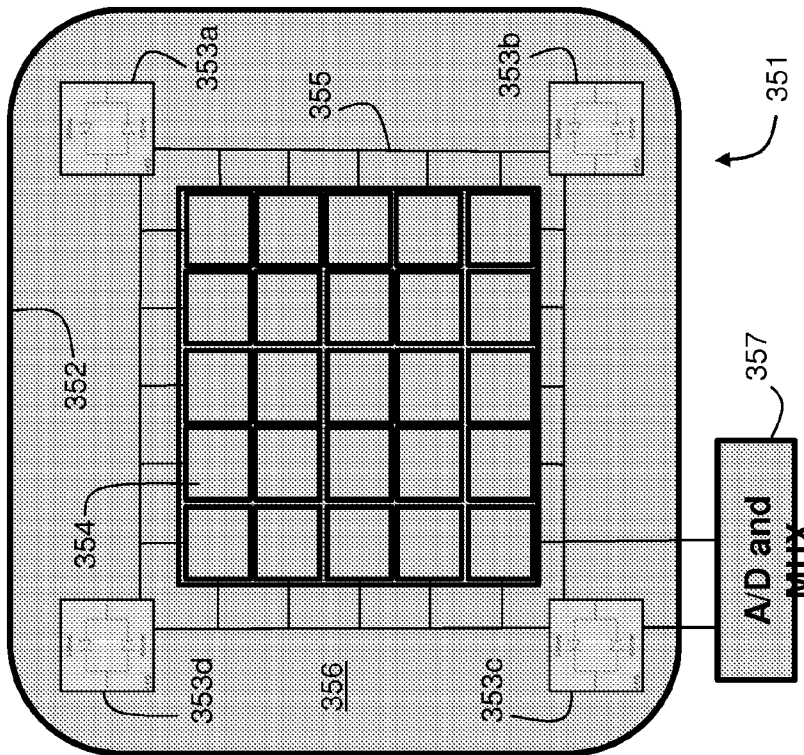


Fig. 27

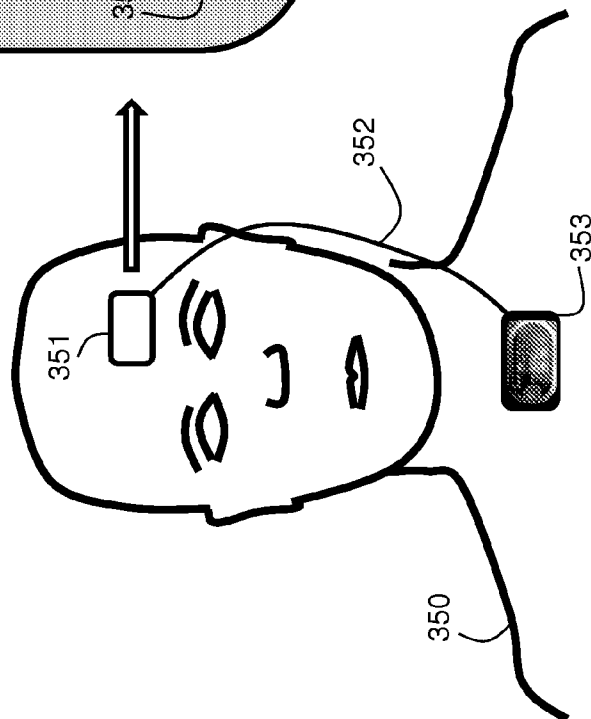


Fig. 26

Array Detector

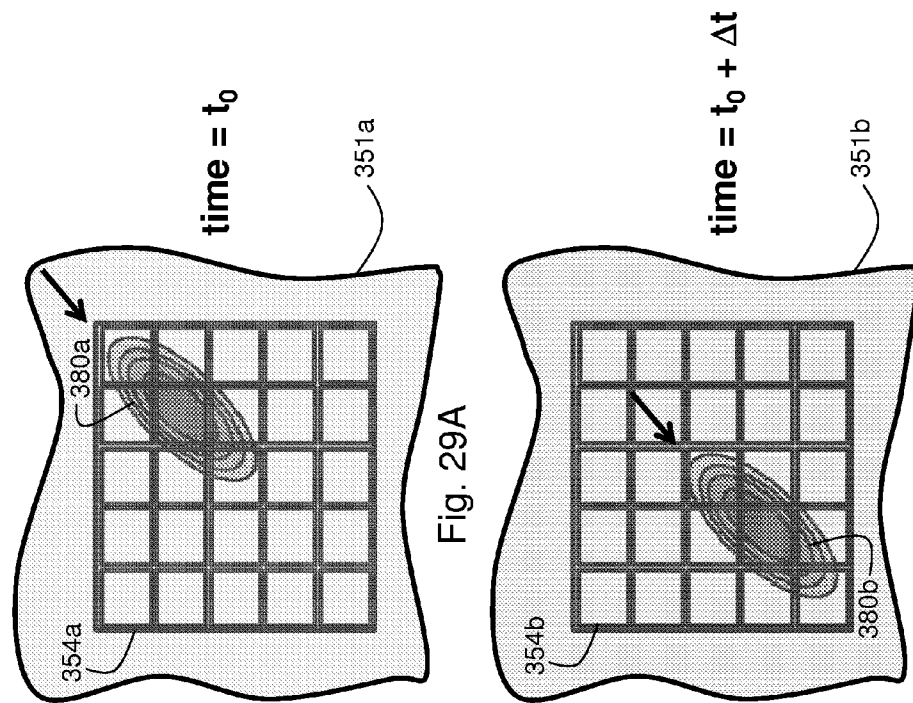


Fig. 29A

Fig. 29B

Single-Pixel Detector

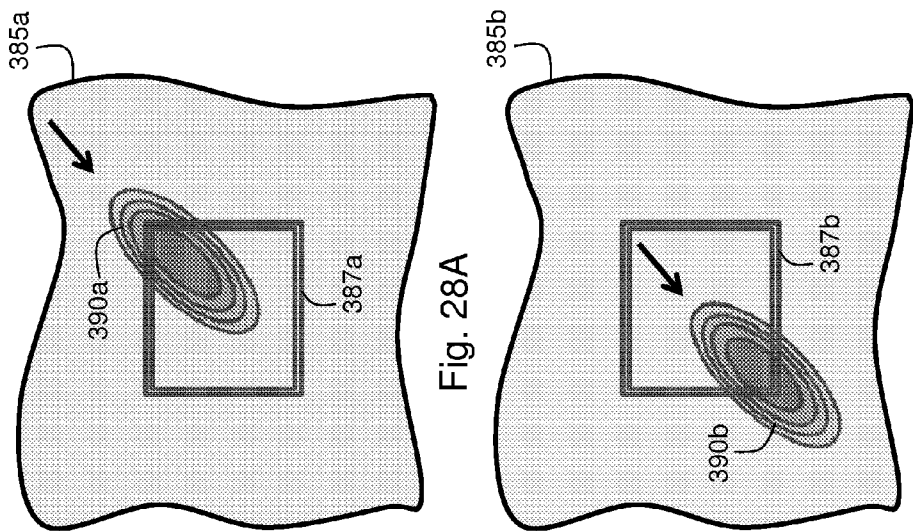
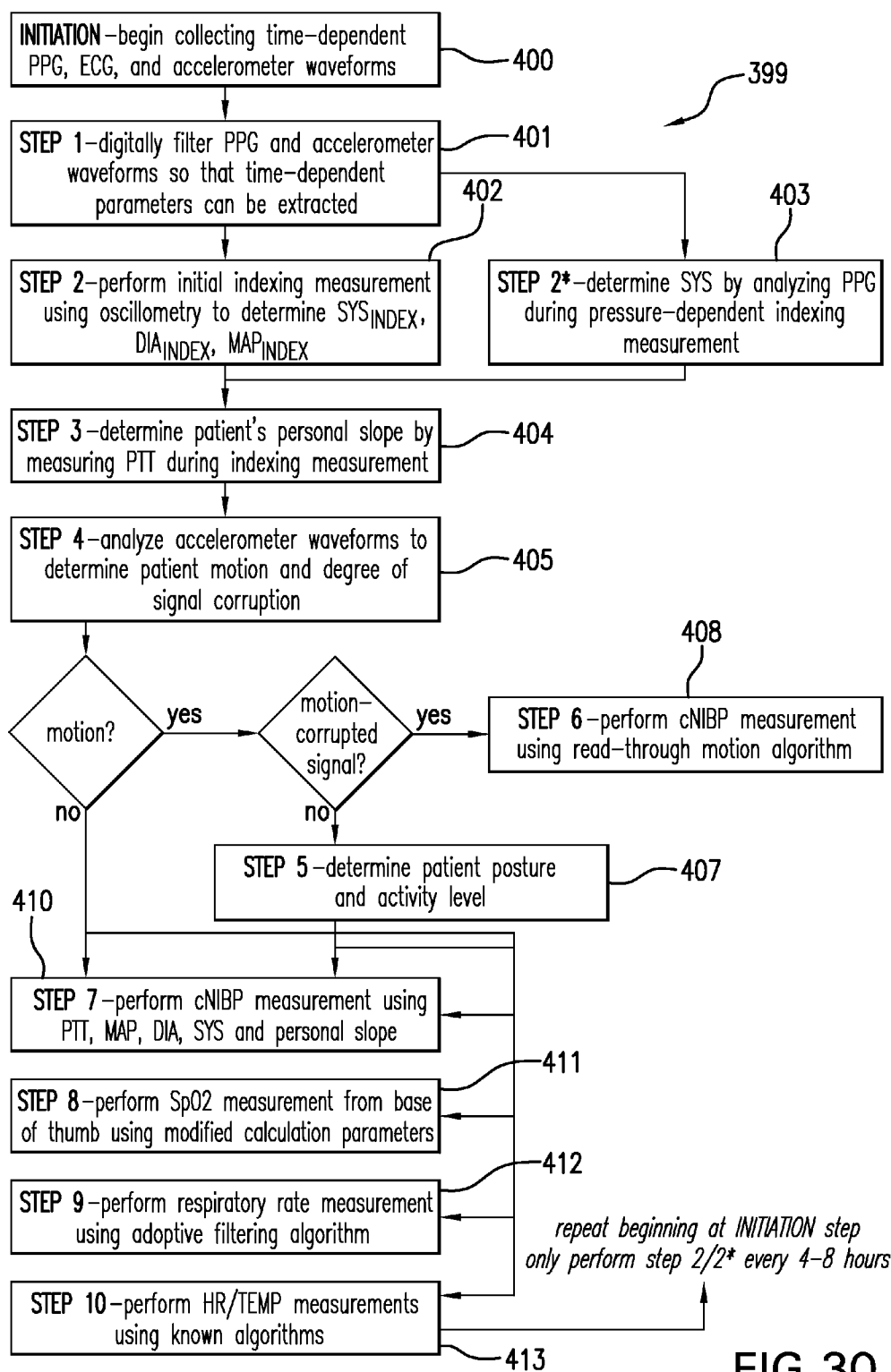


Fig. 28A

Fig. 28B



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BODY-WORN SYSTEM FOR MEASURING CONTINUOUS NON-INVASIVE BLOOD PRESSURE (CNIBP)

CROSS REFERENCES TO RELATED APPLICATIONS

[0001] This application is a Continuation-in-Part of co-pending U.S. patent application Ser. No. 12/138,194, filed Jun. 12, 2008, entitled VITAL SIGN MONITOR FOR MEASURING BLOOD PRESSURE USING OPTICAL, ELECTRICAL, AND PRESSURE WAVEFORMS, which claims the benefit of U.S. Provisional Application No. 60/943,464, filed Jun. 12, 2007, and of U.S. Provisional Application No. 60/983,198, filed Oct. 28, 2007; all of which are incorporated herein by reference.

BACKGROUND OF THE INVENTION

[0002] Pulse transit time (PTT), defined as the transit time for a pressure pulse launched by a heartbeat in a patient's arterial system, has been shown in a number of studies to correlate to both systolic and diastolic blood pressure. In these studies, PTT is typically measured with a conventional vital signs monitor that includes separate modules to determine both an electrocardiogram (ECG waveform) and pulse oximetry (SpO₂). During a PTT measurement, multiple electrodes typically attach to a patient's chest to determine a time-dependent component of the ECG waveform characterized by a sharp spike called the 'QRS complex'. The QRS complex indicates an initial depolarization of ventricles within the heart and, informally, marks the beginning of the heartbeat and a pressure pulse that follows. SpO₂ is typically measured with a bandage or clothespin-shaped sensor that attaches to a patient's finger, and includes optical systems operating in both red and infrared spectral regions. A photodetector measures radiation emitted from the optical systems that transmits through the patient's finger. Other body sites, e.g., the ear, forehead, and nose, can also be used in place of the finger. During a measurement, a microprocessor analyses both red and infrared radiation measured by the photodetector to determine time-dependent waveforms corresponding to the different wavelengths called photoplethysmographs ('PPG waveforms'). From these a SpO₂ value is calculated. Time-dependent features of the PPG waveform indicate both pulse rate and a volumetric absorbance change in an underlying artery (e.g., in the finger) caused by the propagating pressure pulse.

[0003] Typical PTT measurements determine the time separating a maximum point on the QRS complex (indicating the peak of ventricular depolarization) and a portion of the PPG waveform (indicating the arrival of the pressure pulse). PTT depends primarily on arterial compliance, the propagation distance of the pressure pulse (which is closely approximated by the patient's arm length), and blood pressure. To account for patient-specific properties, such as arterial compliance, PTT-based measurements of blood pressure are typically 'calibrated' using a conventional blood pressure cuff. Typically during the calibration process the blood pressure cuff is applied to the patient, used to make one or more blood pressure measurements, and then removed. Going forward, the calibration measurements are used, along with a change in PTT, to determine the patient's blood pressure and blood

pressure variability. PTT typically relates inversely to blood pressure, i.e., a decrease in PTT indicates an increase in blood pressure.

[0004] A number of issued U.S. patents describe the relationship between PTT and blood pressure. For example, U.S. Pat. Nos. 5,316,008; 5,857,975; 5,865,755; and 5,649,543 each describe an apparatus that includes conventional sensors that measure ECG and PPG waveforms, which are then processed to determine PTT.

SUMMARY OF THE INVENTION

[0005] This invention provides a technique for continuous measurement of blood pressure (cNIBP), based on PTT, which features a number of improvements over conventional PTT measurements. Referred to herein as the 'Composite Method', the invention uses a body-worn monitor that measures cNIBP and other vital signs, and wirelessly transmits them to a remote monitor, such as a tablet PC, workstation at a nursing station, personal digital assistant (PDA), or cellular telephone. The body-worn monitor features a wrist-worn transceiver that receives and processes signals generated by a network of body-worn sensors. During a measurement these sensors are typically placed on the patient's arm and chest and measure time-dependent ECG, PPG, pressure, and accelerometer waveforms. Sensors within the network typically include a cuff with an inflatable air bladder, at least three electrical sensors (e.g. ECG electrodes), three accelerometers, and an optical sensor (e.g., a light source and photodiode) typically worn around the patient's thumb. They measure signals that are processed according to the Composite Method to determine blood pressure, and with other algorithms to determine vital signs such as SpO₂, respiration rate, heart rate, temperature, and motion-related properties such as motion, activity level, and posture. The body-worn monitor then wirelessly transmits this information (typically using a two-way wireless protocol, e.g. 802.15.4 or 802.11) to the remote monitor. The monitor displays both vital signs and the time-dependent waveforms. Both the monitor and the wrist-worn transceiver can additionally include a barcode scanner, touch screen display, camera, voice and speaker system, and wireless systems that operate with both local-area networks (e.g. 802.11 or 'WiFi' networks) and wide-area networks (e.g. the Sprint network) to transmit and display information.

[0006] The Composite Method includes both pressure-dependent and pressure-free measurements. It is based on the discovery that PTT and the PPG waveform used to determine it are strongly modulated by an applied pressure. During a pressure-dependent measurement, also referred to herein as an 'indexing measurement', two events occur as the pressure gradually increases to the patient's systolic pressure: 1) PTT increases, typically in a non-linear manner, once the applied pressure exceeds diastolic pressure; and 2) the magnitude of the PPG's amplitude systematically decreases, typically in a linear manner, as the applied pressure approaches systolic pressure. The applied pressure gradually decreases blood flow and consequent blood pressure in the patient's arm, and therefore induces the pressure-dependent increase in PTT. Each of the resulting pairs of PTT/blood pressure readings measured during the period of applied pressure can be used as a calibration point. Moreover, when the applied pressure equals systolic blood pressure, the amplitude of the PPG waveform is completely eliminated, and PTT is no longer measurable. Collectively analyzing both PTT and the PPG waveform's amplitude over a suitable range, along with the

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pressure waveform using techniques borrowed from conventional oscillometry, yields the patient's systolic (SYS), diastolic (DIA), and mean (MAP) arterial pressures, along with a patient-specific slope relating PTT and MAP. From these parameters the patient's cNIBP can be determined without using a conventional cuff.

[0007] A combination of several algorithmic features improves the efficacy of the Composite Method over conventional PTT measurements of cNIBP. For example, sophisticated, real-time digital filtering removes high-frequency noise from the PPG waveform, allowing its onset point to be accurately detected. When processed along with the ECG waveform, this ensures measurement of an accurate PTT and, ultimately, cNIBP value. The pressure-dependent indexing method, which is made during inflation of the arm-worn cuff, yields multiple data points relating PTT and blood pressure during a short (~60 second) measurement. Processing of these data points yields an accurate patient-specific slope relating PTT to cNIBP. Inclusion of multiple accelerometers yields a variety of signals that can determine features like arm height, motion, activity level, and posture that can be further processed to improve accuracy of the cNIBP calculation, and additionally allow it to be performed in the presence of motion artifacts. And a model based on femoral blood pressure, which is more representative of pressure in the patient's core, can reduce effects such as 'pulse pressure amplification' that can elevate blood pressure measured at a patient's extremities.

[0008] The Composite Method can also include an 'intermediate' pressure-dependent measurement wherein the cuff is partially inflated. This partially decreases the amplitude of the PPG waveform in a time-dependent manner. The amplitude's pressure-dependent decrease can then be 'fit' with a numerical function to estimate the pressure at which the amplitude completely disappears, indicating systolic pressure.

[0009] For the pressure-dependent measurement, a small pneumatic system attached to the cuff inflates the bladder to apply pressure to an underlying artery according to the pressure waveform. The cuff is typically located on the patient's upper arm, proximal to the brachial artery, and time-dependent pressure is measured by an internal pressure sensor, such as an in-line Wheatstone bridge or strain gauge, within the pneumatic system. The pressure waveform gradually ramps up in a mostly linear manner during inflation, and then slowly rapidly deflates through a 'bleeder valve' during deflation. During inflation, mechanical pulsations corresponding to the patient's heartbeats couple into the bladder as the applied pressure approaches DIA. The mechanical pulsations modulate the pressure waveform so that it includes a series of time-dependent oscillations. The oscillations are similar to those measured with an automated blood pressure cuff using oscillometry, only they are measured during inflation rather than deflation. They are processed as described below to determine a 'processed pressure waveform', from which MAP is determined directly, and SYS and DIA are determined indirectly.

[0010] Pressure-dependent measurements performed on inflation have several advantages to similar measurements performed on deflation, which are convention. For example, inflation-based measurements are relatively fast and comfortable compared to those made on deflation. Most conventional cuff-based systems using deflation-based oscillometry take roughly 4 times longer than the Composite Method's pres-

sure-dependent measurement. Inflation-based measurements are possible because of the Composite Method's relatively slow inflation speed (typically 5-10 mmHg/second) and high sensitivity of the pressure sensor used within the body-worn monitor. Moreover, measurements made during inflation can be immediately terminated once systolic blood pressure is calculated. In contrast, conventional cuff-based measurements made during deflation typically apply a pressure that far exceeds the patient's systolic blood pressure; pressure within the cuff then slowly bleeds down below DIA to complete the measurement.

[0011] Pressure-free measurements immediately follow the pressure-dependent measurements, and are typically made by determining PTT with the same optical and electrical sensors used in the pressure-dependent measurements. Specifically, the body-worn monitor processes PTT and other properties of the PPG waveform, along with the patient-specific slope and measurements of SYS, DIA, and MAP made during the pressure-dependent measurement, to determine cNIBP.

[0012] In addition to blood pressure, the body-worn monitor measures heart rate (HR), SpO₂, and respiratory rate from components of the ECG, PPG, and accelerometer waveforms. A body-worn thermocouple measures temperature. These measurements, along with those used to process accelerometer waveforms to determine motion, posture, and activity level, are made using algorithms described below.

[0013] In one aspect, the invention provides a body-worn monitor, described in detail below, which measures cNIBP from an ambulatory patient according to the Composite Method. The body-worn monitor features: (1) a pressure-delivery and sensor system that applies a variable pressure to the patient's arm and, in response, measures a time-dependent pressure waveform; (2) a first sensor (e.g. an optical sensor) that generates a first time-dependent waveform representing a flow of blood within the patient; and (3) a second sensor (e.g. an ECG circuit and electrodes) that generates a second time-dependent waveform representing contractile properties of the patient's heart. A processing component receives information from these sensors, and processes it to: (1) determine a PTT between features in the first and second waveforms; (2) determine a mathematical relationship between PTT and blood pressure in the patient's core region (e.g. femoral artery); and iii) analyze a PTT and the mathematical relationship to generate a blood pressure indicative of the patient's core region. The processing component is typically located in the wrist-worn transceiver.

[0014] In embodiments, the ECG circuit within the body-worn monitor features a single circuit (e.g. an ASIC) that collects electrical signals from a series of body-worn electrodes and converts these signals into a digital ECG waveform. Such a circuit is typically worn directly on the patient's chest, and connects to the wrist-worn transceiver through a digital, serial interface (e.g. an interface based on a 'control area network', or 'CAN', system). The optical sensor typically includes optics for measuring signals relating to both cNIBP and SpO₂, and typically features a ring-like form factor that comfortably wraps around the base of the patient's thumb. All of these systems are described in detail below.

[0015] In embodiments, both the first and second sensors feature transducers for measuring optical, pressure, acoustic, and electrical impedance signals, as well as electrical components for measuring ECG waveforms. In general, PTT can be determined from various combinations of these signals,

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e.g. between any two signals measured by a transducer, or between an ECG waveform and a second signal measured by a transducer. In preferred embodiments, the first sensor measures a PPG waveform, the second sensor measures an ECG waveform, and the processing component determines PTT from a QRS complex in an ECG waveform and an onset point of the PPG waveform. The processing component then analyzes PTT measured as pressure is applied to determine its relationship to MAP in the patient's femoral artery. In embodiments, this relationship is characterized by the following Equation, or a mathematical derivative thereof:

$$\frac{MAP_{femoral}}{MAP_{INDEX}} = (m_{femoral} \times PTT) - (m_{femoral} \times PTT_{INDEX}) +$$

wherein $MAP_{femoral}$ represents blood pressure in the patient's femoral artery, PTT represents pulse transit time measured from the first and second waveforms, PTT_{INDEX} represents a pulse transit time determined before PTT (and typically immediately before the pressure-dependent indexing measurement), $m_{femoral}$ represents a mathematical slope representing a relationship between $MAP_{femoral}$ and PTT, and MAP_{INDEX} represents a mean arterial pressure determined from the time-dependent pressure waveform. In the Equation above, $m_{femoral}$ is typically determined by collectively processing the first, second, and pressure waveforms. For example, it can be determined by processing a set of PTT values measured while time-dependent pressure is applied to the patient's arm, and then fitting the set with a linear equation to estimate a patient-specific relationship between PTT and MAP. This relationship, which is determined during the pressure-dependent indexing measurement, forms part of a 'calibration' for cuffless, PTT-based cNIBP measurement made afterwards. Other calibration parameters determined during the indexing measurement are SYS, DIA, and relationships between these parameters and MAP. These values are determined directly from a pressure waveform, typically measured during inflation using techniques derived from oscillometry. In embodiments, during an indexing measurement a digital filter, typically implemented with a software-based algorithm, processes the time-dependent pressure waveform to determine a 'processed pressure waveform'. The digital filter, for example, can be a 2-stage filter featuring a digital band-pass filter, followed by a digital low-pass filter. From the processed pressure waveform SYS, DIA, and MAP can be determined.

[0016] In other embodiments, the relationship between SYS, DIA, and MAP depends on the patient's HR, which is typically determined from either the ECG or PPG waveform. In still other embodiments, the relationship between PTT and MAP is non-adjustable and determined beforehand, e.g. from a group of patients in a clinical study. During an actual measurement, such a relationship is typically used as a default case when a patient-specific relationship cannot be accurately determined (because, e.g., of PPG or ECG waveforms corrupted by motion-related noise). Typically the relationship between PTT and MAP in the patient's femoral artery is between 0.5 mmHg/ms and 1.5 mmHg/ms.

[0017] In another aspect, the patient-specific indexing measurement involves estimating an 'effective MAP' in the patient's arm that varies with pressure applied by the pressure-delivery system. The effective MAP is the difference between MAP determined during the inflation in the indexing measurement and a pressure-induced blood pressure change, caused by an arm-worn cuff featuring an inflatable bladder. In

embodiments, the pressure-induced blood pressure change is defined by the following equation or a mathematical derivative thereof:

$$\Delta MAP(P) = F \times (P_{applied} - DIA_{INDEX})$$

where $\Delta MAP(P)$ is the pressure-induced blood pressure change, $P_{applied}$ is pressure applied by the pressure-delivery system during inflation, DIA_{INDEX} is the diastolic pressure determined from the processed pressure waveform during the indexing measurement, and F is a mathematical constant.

[0018] In embodiments, the indexing measurement is performed once every 4 hours or more, and a PTT-based cNIBP measurement is performed once every 1 second or less. Typically, PTT values are averaged from a set of values collected over a time period between, typically ranging from 10 to 120 seconds. The average is typically a 'rolling average' so that a new value, determined over the averaging period, can be displayed relatively frequently (e.g. every second).

[0019] In another aspect, the invention provides a method for monitoring a blood pressure value from a patient, which features determining a PTT value from a patient, as described above, from PPG and ECG waveforms. Additionally, HR is determined by analyzing QRS complexes in the ECG waveform. During the measurement, the processing component determines a mathematical relationship between HR (or a parameter calculated therefrom), and PTT (or a parameter calculated therefrom). At a later point in time, the processing component uses the mathematical relationship and a current value of HR to estimate PTT and, ultimately, a based blood pressure value. This method would be deployed, for example, when motion-related noise corrupts the PPG waveform (which is relatively sensitive to motion), but not the ECG waveform (which is relatively immune to motion).

[0020] In embodiments, the method measures a first set of HR values and a second set of PTT values, and then processes the first and second sets to determine the mathematical relationship between them. The first and second sets are typically measured prior to measuring the HR used to estimate PTT, and are typically collected over a time period ranging between 5 and 60 seconds. Paired HR/PTT values collected during the time period are then analyzed, typically by fitting them using a linear regression algorithm, to determine a mathematical relationship relating HR to PTT. Alternatively a non-linear fitting algorithm, such as the Levenburg-Marquardt algorithm, can be used to determine a non-linear relationship between HR and PTT. The non-linear relationship can be characterized, e.g., by a second or third-order polynomial, or by an exponential function.

[0021] As described above, this algorithm is typically performed when a patient's motion makes it difficult or impossible to accurately calculate PTT from the PPG waveform. The algorithm can be initiated when analysis of a pulse in the PPG waveform indicates PTT cannot be measured. Alternatively, the algorithm is initiated when analysis of at least one 'motion waveform' (e.g. an accelerometer waveform generated from one or more signals from an accelerometer) indicates that the PPG waveform is likely corrupted by motion. Analysis of the motion waveform can involve comparing a portion of it to a predetermined threshold, or analyzing it with a mathematical model, to determine if an accurate PTT can be calculated.

[0022] In a related aspect, the invention provides another algorithm that allows PTT-based cNIBP to be determined in the presence of motion. In this case, rather than estimating

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PTT from HR using a mathematical model, the algorithm 'reconstructs' motion-corrupted pulses in the PPG waveform through analysis of separate PPG waveforms measured simultaneously with two separate light sources. A pulse oximeter sensor, such as that included in the body-worn monitor described in detail below, includes a first light source operating in a red spectral region (between 590 and 700 nm, and preferably about 660 nm), and a second light source operating in the infrared spectral region (between 800 and 1000 nm, and preferably around 905 nm), and can therefore be used for this purpose.

[0023] The algorithm features: 1) collectively processing unique PPG waveforms to generate a processed signal; 2) processing the processed signal with a digital filter to generate a filtered signal; 3) analyzing the filtered signal to determine a feature related to blood pressure; and 4) analyzing the feature related to blood pressure to determine the blood pressure value. In embodiments, the processing component is programmed to collectively process the first and second signals by subtracting one signal from the other, or dividing one signal into the other, to generate the processed signal. This signal is then filtered with a digital bandpass filter, typically characterized by a passband between 0.01→5.0 Hz, to generate the filtered signal. The filtered signal is typically relatively free of motion artifacts, and yields an onset point which can be combined with an ECG QRS complex to determine PTT and then cNIBP. As described above, this algorithm can be initiated by processing an accelerometer waveform which indicates that a patient is moving, or by processing the PPG waveforms to determine that they are corrupted in any way. In other embodiments, steps in the algorithm are rearranged so that the corrupted PPG waveforms are first filtered with a digital bandpass filter, and then these filtered waveforms are subtracted from each other or divided into each other, and then processed to determine an onset point.

[0024] In another aspect, the body-worn monitor's optical sensor described above features a detector that includes at least two pixel elements, each configured to generate a unique signal. A processing component within the monitor is configured to: (1) analyze a signal generated by a first pixel element; (2) analyze a signal generated by a second pixel element; (3) analyze a signal indicating motion, e.g. an accelerometer waveform; (4) based on analysis of the motion signal, select a signal from at least one of the pixel elements characterized by a relatively low degree of motion corruption; and (5) analyze the selected signal to determine a vital sign value, e.g. cNIBP.

[0025] In embodiments, the multi-pixel detector features at least a 3×3 array of pixels, each containing a photodetector. In this case the optical sensor is integrated with a circuit configured to de-multiplex signals from the multi-pixel detector. The processor in the body-worn monitor can be programmed to analyze the motion signal and a signal from each pixel element to determine the signal that has the lowest correlation to the motion signal, indicating that the signal is characterized by a relatively low degree of motion corruption. Correlation, for example, can be determined using standard algorithms known in the art, such as algorithms that determine cross-correlation between two sequences of data points. Such algorithms can yield a Gaussian-type waveform, with the amplitude of the waveform increasing with correlation. The waveform can then be compared to a series of metrics to determine a numerical figure of merit indicating the degree of correlation. Alternatively, the processor is programmed to

analyze the motion signal to determine a measurement period when patient movement is relatively low, and then measure a signal from each pixel element. In both cases, the signal from each pixel element represents a PPG waveform featuring a sequence of pulses, each characterized by an onset point. When combined with an ECG QRS complex, this waveform can yield a PTT as described above. In embodiments the multi-pixel detector is included in the thumb-worn sensor described in detail below. Alternatively, it is incorporated in a flexible patch configured to be worn on the patient's forehead. In this case the flexible patch connects to a body-worn transceiver that is similar to the wrist-worn transceiver in both form and function.

BRIEF DESCRIPTION OF THE DRAWINGS

[0026] FIGS. 1A and 1B show, respectively, schematic drawings indicating the Composite Method's pressure-dependent and pressure-free measurements;

[0027] FIGS. 2A and 2B show graphs of, respectively, PTT and the amplitude of the PPG waveform measured as a function of pressure;

[0028] FIG. 3A shows a graph of PTT measured as a function of 'effective' mean arterial blood pressure (MAP*(P)) determined using the Composite Method's pressure-dependent measurement;

[0029] FIG. 3B shows a graph of PTT measured as a function of mean arterial blood pressure (MAP) determined using a conventional blood pressure measurement of the prior art;

[0030] FIG. 4A shows a graph of PTT measured as a function of both MAP*(P) (measured during inflation using the Composite Method's pressure-dependent measurement) and MAP (measured for two separate blood pressure values using oscillometry) for a single patient;

[0031] FIG. 4B shows a graph of PTT measured as a function of both MAP*(P) (measured during deflation using the Composite Method's pressure-dependent measurement) and MAP (measured for two separate blood pressure values) for a single patient;

[0032] FIGS. 5A and 5B show graphs of, respectively, a time-dependent pressure waveform measured during both inflation and deflation, and the same waveform after being filtered with a digital bandpass filter;

[0033] FIG. 6 shows a graph of amplitudes corresponding to heartbeat-induced pulses taken from the inflationary portion of the graph in FIG. 5B and plotted as a function of pressure applied to a patient's brachial artery;

[0034] FIG. 7A shows a graph of time-dependent ECG and PPG waveforms and markers associated with these waveforms used to determine PTT;

[0035] FIG. 7B shows a graph of the time-dependent PPG waveform of FIG. 7A (top trace), the first derivative of the waveform (middle trace), and the second derivative of the PPG waveform (bottom trace);

[0036] FIG. 8 is a schematic drawing showing a sequence of pressure-dependent and pressure-free measurements made during the Composite Method;

[0037] FIG. 9 is a schematic drawing showing how, during a clinical trial, an indexing measurement is made from the patient's brachial artery, and a reference measurement using an A-line is made from the patient's femoral artery;

[0038] FIG. 10 shows a graph of time-dependent SYS values measured with the Composite Method (black trace), a femoral A-line (dark gray trace), and a radial A-line (light gray trace);

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[0039] FIG. 11 shows a graph of time-dependent SYS and DIA values measured with the Composite Method (gray trace) and SYS and DIA measured with a femoral A-line;

[0040] FIG. 12 shows a graph of a histogram of standard deviation values for SYS (dark bars) and DIA (light bars) measured during a 23-subject clinical trial;

[0041] FIG. 13 shows a bar graph of FDA standard values and statistics from the 23-subject study calculated using an ANOVA and AVERAGE methodologies for, respectively, intra-subject BIAS and STDEV for SYS (upper and lower left-hand corners); and intra-subject BIAS and STDEV for DIA (upper and lower right-hand corners);

[0042] FIG. 14 shows a table of drift of the SYS and DIA measurements made according to the Composite Method corresponding, respectively, to 4 and 8-hour indexing periods;

[0043] FIG. 15 shows a graph of a time-dependent PPG waveform measured with and without motion using an IR LED (top trace), a RED LED (second trace), the waveform measured with the IR LED divided by the waveform measured with the RED LED (third trace), and the third trace processed with a digital bandpass filter (fourth trace);

[0044] FIG. 16 shows a graph of a time-dependent PPG waveform measured with and without motion using an IR LED (top trace), a RED LED (second trace), the waveform measured with the RED LED subtracted from the waveform measured with the IR LED (third trace), and the third trace processed with a digital bandpass filter (fourth trace);

[0045] FIG. 17 shows a graph of a time-dependent PPG waveform measured with and without motion using an IR LED and processed with a digital bandpass filter (top trace), a RED LED and processed with a digital bandpass filter (second trace), and the second trace subtracted from the first trace (third trace);

[0046] FIG. 18 shows a schematic drawing indicating an algorithm that allows cNIBP measurements to be made in both the presence and absence of motion;

[0047] FIG. 19 shows a graph of time-dependent PTT and HR measurements, and how these can be processed with the algorithm shown in FIG. 18 to measure cNIBP in presence of motion;

[0048] FIGS. 20A and 21A show, respectively, time-dependent SYS waveforms made using a femoral A-line (dark gray) and reconstructed using the algorithm shown in FIGS. 18 and 19 to yield the best and worst results for the 23 clinical subjects;

[0049] FIGS. 20B and 21B show, respectively, correlation plots generated using data from FIGS. 20A and 21A;

[0050] FIG. 22 shows a schematic view of a patient and a coordinate axis used with an algorithm and accelerometer waveforms to determine the patient's posture;

[0051] FIG. 23A shows a graph of time-dependent accelerometer waveforms measured from a patient's chest during different postures;

[0052] FIG. 23B shows a graph of time-dependent postures determined by processing the accelerometer waveforms of FIG. 23A with an algorithm and the coordinate axis shown in FIG. 22;

[0053] FIGS. 24A and 24B show, respectively, a three-dimensional image of the body-worn monitor of the invention attached to a patient during and after an initial indexing measurement;

[0054] FIG. 25 shows a three-dimensional image of the wrist-worn transceiver used with the body-worn monitor of FIGS. 24A and 24B;

[0055] FIG. 26 shows an image of a patient wearing a head-mounted sensor featuring a multi-pixel array photodetector for measuring a PPG waveform according to an alternate embodiment of the invention;

[0056] FIG. 27 shows a plan view of the multi-pixel array photodetector of FIG. 26;

[0057] FIGS. 28A and 28B show a bolus of blood passing through a detecting area of a conventional single-pixel photodetector for measuring a PPG waveform;

[0058] FIGS. 29A and 29B show a bolus of blood passing through a detecting area of the multi-pixel array photodetector of FIGS. 26 and 27; and

[0059] FIG. 30 shows a flow chart for measuring cNIBP, SpO₂, respiration rate, heart rate, temperature, and motion according to the invention.

DETAILED DESCRIPTION OF THE INVENTION

Theory of the Composite Method

[0060] FIGS. 1A and 1B show schematic drawings of the Composite Method's pressure-free (FIG. 1A) and pressure-dependent (FIG. 1B) measurements. Working in concert, these measurements accurately determine the patient's cNIBP for an extended time without requiring an external calibration device, e.g., a conventional blood pressure cuff. During a measurement, the patient wears a body-worn monitor attached to a disposable cuff and collection of optical, electrical, motion, and temperature sensors. These sensors measure signals for both the pressure-dependent and pressure-free measurements. The co-pending patent applications, the contents of which are fully incorporated herein by reference, describe earlier embodiments of this measurement: DEVICE AND METHOD FOR DETERMINING BLOOD PRESSURE USING 'HYBRID' PULSE TRANSIT TIME MEASUREMENT (U.S. Ser. No. 60/943,464; filed Jun. 12, 2007); VITAL SIGN MONITOR FOR CUFFLESSLY MEASURING BLOOD PRESSURE USING A PULSE TRANSIT TIME CORRECTED FOR VASCULAR INDEX (U.S. Ser. No. 60/943,523; filed Jun. 12, 2007); and VITAL SIGN MONITOR FOR MEASURING BLOOD PRESSURE USING OPTICAL, ELECTRICAL, AND PRESSURE WAVEFORMS (U.S. Ser. No. 12/138,194; filed Jun. 12, 2008). A microprocessor in the body-worn monitor processes the PPG and ECG waveforms to determine PTT, which is used in both measurements of the Composite Method to determine cNIBP, as is described in more detail below.

[0061] The cuff includes an air bladder which, when pressurized with a pneumatic system, applies a pressure 107 to an underlying artery 102, 102'. An electrical system featuring at least 3 electrodes coupled to an amplifier/filter circuit within cabling attached to the wrist-worn transceiver measures an ECG waveform 104, 104' from the patient. Three electrodes (two detecting positive and negative signals, and one serving as a ground) are typically required to detect the necessary signals to generate an ECG waveform with an adequate signal-to-noise ratio. At the same time, an optical system featuring a transmissive or, optionally, reflective optical sensor measures a PPG waveform 105, 105' featuring a series of 'pulses', each characterized by an amplitude of AMP_{1/2}, from the patient's artery. The preferred measurement site is typically near small arteries in the patient's thumb, such as the princeps pollicis artery. A microprocessor and analog-to-digital converter within the wrist-worn transceiver detects and analyzes the ECG 104, 104' and PPG 105, 105' wave-

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forms to determine both PTT_1 (from the pressure-free measurement) and PTT_2 (from the pressure-dependent measurement). Typically the microprocessor determines both PTT_1 and PTT_2 by calculating the time difference between the peak of the QRS complex in the ECG waveform **104**, **104'** and the foot (i.e. onset) of the PPG waveform **105**, **105'**.

[0062] The invention is based on the discovery that an applied pressure (indicated by arrow **107**) during the pressure-dependent measurement affects blood flow (indicated by arrows **103**, **103'**) in the underlying artery **102**, **102'**. Specifically, the applied pressure has no effect on either PTT_2 or AMP_2 when it is less than a diastolic pressure within the artery **102**, **102'**. When the applied pressure **107** reaches the diastolic pressure it begins to compress the artery, thus reducing blood flow and the effective internal pressure. This causes PTT_2 to systematically increase relative to PTT_1 , and AMP_2 to systematically decrease relative to AMP_1 . PTT_2 increases and AMP_2 decreases (typically in a linear manner) as the applied pressure **107** approaches the systolic blood pressure within the artery **102**, **102'**. When the applied pressure **107** reaches the systolic blood pressure, AMP_2 is completely eliminated and PTT_2 consequently becomes immeasurable.

[0063] During a measurement the patient's heart generates electrical impulses that pass through the body near the speed of light. These impulses accompany each heartbeat, which then generates a pressure wave that propagates through the patient's vasculature at a significantly slower speed. Immediately after the heartbeat, the pressure wave leaves the heart and aorta, passes through the subclavian artery, to the brachial artery, and from there through the radial and ulnar arteries to smaller arteries in the patient's fingers. Three disposable electrodes located on the patient's chest measure unique electrical signals which pass to an amplifier/filter circuit within the body-worn monitor. Typically, these electrodes attach to the patient's chest in a 1-vector 'Einthoven's triangle' configuration to measure unique electrical signals. Within the body-worn monitor, the signals are processed using the amplifier/filter circuit to determine an analog electrical signal, which is digitized with an analog-to-digital converter to form the ECG waveform and then stored in memory. The optical sensor typically operates in a transmission-mode geometry, and includes an optical module featuring an integrated photodetector, amplifier, and pair of light sources operating at red (~660 nm) and infrared (~905 nm) wavelengths. These wavelengths are selected because they are effective at measuring PPG waveforms with high signal-to-noise ratios that can additionally be processed to determine SpO₂. In alternative embodiments, an optical sensor operating in a reflection-mode geometry using green (~570 nm) wavelengths can be used in place of the transmission-mode sensor. Such a sensor has the advantage that it can be used at virtually any location on the patient's body. The green wavelength is chosen because it is particularly sensitive to volumetric absorbance changes in an underlying artery for a wide variety of skin types when deployed in a reflection-mode geometry, as described in the following co-pending patent application, the entire contents of which are incorporated herein by reference: SYSTEM FOR MEASURING VITAL SIGNS USING AN OPTICAL MODULE FEATURING A GREEN LIGHT SOURCE (U.S. Ser. No. 11/307,375; filed Feb. 3, 2006).

[0064] The optical sensor detects optical radiation modulated by the heartbeat-induced pressure wave, which is further processed with a second amplifier/filter circuit within the wrist-worn transceiver. This results in the PPG waveform,

which, as described above, includes a series of pulses, each corresponding to an individual heartbeat. Likewise, the ECG waveforms from each measurement feature a series of sharp, 'QRS' complexes corresponding to each heartbeat. As described above, pressure has a strong impact on amplitudes of pulses in the PPG waveform during the pressure-dependent measurement, but has basically no impact on the amplitudes of QRS complexes in the corresponding ECG waveform. These waveforms are processed as described below to determine blood pressure.

[0065] The Composite Method performs an indexing measurement once every 4-8 hours using inflation-based oscillometry. During the indexing measurement, a linear regression model is used to relate the pressure applied by the cuff to an 'effective MAP' (referred to as $MAP^*(P)$ in FIG. 3A) representing a mean pressure in the patient's arm. $MAP^*(P)$ and the PTT value associated with it vary tremendously during an inflationary process. As shown in FIG. 3A, this results in a unique set of $MAP^*(P)/PTT$ paired data points which can be extracted for each heartbeat occurring as the applied pressure ramps from DIA to SYS. This means calibration can be performed with a single, inflation-based measurement that typically takes between 40-60 seconds. At a recommended inflation rate (approximately 3-10 mmHg/second, and most preferably about 5 mmHg/second) this typically yields between 5-15 data points. These are the data points analyzed with the linear regression model to determine the patient-specific slope. Blood pressure values (SYS_{INDEX} , MAP_{INDEX} , and DIA_{INDEX}) and the ratios between them ($R_{SYS}=SYS_{INDEX}/MAP_{INDEX}$; $R_{DIA}=DIA_{INDEX}/MAP_{INDEX}$) determined during the inflation-based measurement are also used in this calculation, and then for subsequent pressure-free measurements.

[0066] A stable PTT value is required for accurate indexing, and thus PTT is measured from both the ECG and PPG waveforms for each heartbeat over several 20-second periods prior to inflating the pump in the pneumatic system. The PTT values are considered to be stable, and suitable for the indexing measurement, when the standard deviation of the average PTT values from at least three 20-second periods (PTT_{STDEV}) divided by their mean (PTT_{MEAN}) is less than 7%, i.e.

$$\frac{PTT_{STDEV}}{PTT_{MEAN}} < 0.07 \quad (1)$$

[0067] When this criterion is met the pump is automatically inflated, and the patient-specific slope is then determined as described above. This process is typically repeated every 4-8 hours. Once determined, the slope is analyzed with a series of empirical metrics to ensure that it is both realistic and consistent with those determined with previous trials. An unrealistic personal slope would result, for example, if a motion-related artifact occurred during the indexing measurement. If either the value or the linear fit used to determine it fails to meet these metrics, then a default slope, determined from analyzing arterial line data collected from a large number of patients, is used in its place. Additionally, the above-described model tends to yield relatively inaccurate results for patients with very low slopes (i.e., slopes less than -0.22 mmHg/ms), and for this case a secondary model is therefore used. This model, which is typically determined experimentally on patients having particularly low personal slopes, relates the personal slope to pulse pressure.

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[0068] During an actual pressure-dependent indexing measurement, the body-worn monitor collects data like that shown in FIGS. 2A and 2B, for an individual patient. During a measurement, the microprocessor analyzes the variation between applied pressure and PTT, shown graphically in FIG. 2A, to estimate the relationship between blood pressure and PTT. As shown in Equation (2), below, this relationship is best described with a mathematical model that first estimates how the patient's 'effective' mean arterial blood pressure ($MAP^*(P)$) varies with applied pressure ($P_{applied}$). The model assumes that pressure applied by the cuff occludes the patient's brachial artery, and thus temporarily decreases blood flow. This, in turn, increases blood pressure directly underneath the cuff, and reduces blood pressure in the downstream radial, ulnar, and finger arteries. The net effect is a temporary, pressure-dependent reduction in the patient's mean arterial blood pressure (MAP), indicated in Equation (2) as $\Delta MAP(P)$, during the pressure-dependent measurement. An empirically determined factor (F) accounts for the ratio between the region of increased blood pressure (underneath the cuff; approximately 10 cm) and the larger region of decreased blood pressure (the length of the arm downstream from the cuff; approximately 50 cm). F is typically between 0.6 and 0.9, and is preprogrammed into the algorithm prior to measurement.

$$\Delta MAP(P) = F \times (P_{applied} - DIA_{INDEX}) \quad (2)$$

$$MAP^*(P) = MAP_{INDEX} - \Delta MAP(P)$$

[0069] Using Equation (2), paired values of PTT and $MAP^*(P)$ are determined for each heartbeat as the applied pressure increases from DIA_{INDEX} to MAP_{INDEX} . This approach yields multiple data points during a single pressure-dependent measurement that can then be fit with a mathematical function (e.g. a linear function) relating PTT to $MAP^*(P)$. Typically these parameters are inversely related, i.e. PTT gets shorter and blood pressure increases. In typical embodiments, therefore, an inverse linear relationship determined during the pressure-dependent indexing measurement is then used during subsequent pressure-free measurements to convert the measured PTT into blood pressure values.

[0070] In Equation (2), the values for DIA_{INDEX} and MAP_{INDEX} are determined with an oscillometric blood pressure measurement during inflation. SYS_{INDEX} can either be determined indirectly during the oscillometric blood pressure measurement, or directly by analyzing the pressure-dependent pulse amplitude in the PPG waveform. In this embodiment, as shown in FIG. 2B, the pulse amplitude will gradually reduce with applied pressure, and eventually disappears when this pressure is equal to SYS . A conventional peak-detecting algorithm running on the microprocessor can thus detect the onset of the optical pulse amplitude shown in FIG. 2B to make a direct measurement of systolic blood pressure. Alternatively, a 'fitting' algorithm can model the systematic decrease in pulse amplitude with applied pressure with a mathematical function (e.g. a linear function) to estimate systolic blood pressure.

[0071] FIGS. 3A and 3B show graphs of PTT as a function $MAP^*(P)$ (FIG. 3A) and MAP (FIG. 3B) for a single patient. Each data point **126**, **129** in the graphs includes error bars representing an approximate measurement error. In FIG. 3A, the data points **126** are determined during a single, 30-second pressure-dependent measurement of the Composite Method; each data point represents PTT and $MAP^*(P)$ values for an individual heartbeat. These data points are derived, for

example, by combining measurements similar to those shown in FIG. 2A (PTT as a function of applied pressure) and Equation (2) ($MAP^*(P)$ calculated from applied pressure). In contrast, the two data points **129** in FIG. 3B are derived by simply measuring PTT and MAP during separate blood pressure measurements. Each measurement normally takes about 60 seconds to complete; they are ideally done at separate points in time when the patient's blood pressure (and corresponding PTT) differs by a measurable amount.

[0072] The two graphs illustrate the advantages of determining a patient-specific relationship between PTT and blood pressure during the Composite Method's pressure-dependent measurement. As shown in FIG. 3A, the data points **126** vary over approximately a relatively large range in blood pressure (typically 15 mmHg or more); they are typically tightly correlated, and, despite any measurement error, can be easily fit with a single linear equation ($y = Mx + B$) shown by the dashed line **125**. In contrast, if the patient's blood pressure is relatively stable, the two data points **129** of FIG. 3B can have similar values, even if they are measured several hours apart. These two values can yield fits with different linear equations ($y = M_1x + B_1$ and $y = M_2x + B_2$) even when the measurement error is low. Using an inaccurate linear equation in this instance can, in turn, result in an inaccurate relationship between PTT and blood pressure. Ultimately this adds error to the PTT-based blood pressure measurement.

[0073] FIGS. 4A and 4B show actual PTT vs. $MAP^*(P)$ and MAP data, measured for a single patient, during a pressure-dependent measurement that uses inflation (FIG. 4A) and deflation (FIG. 4B). In the figures the triangles indicate PTT vs. $MAP^*(P)$ determined during the Composite Method's pressure-dependent indexing measurement. These data represent a calibration of the blood pressure measurement. The squares indicate subsequent measurements wherein MAP is determined using an automated blood pressure cuff, and PTT is determined using the body-worn monitor described herein. As is clear from the figures, the values of PTT vs. $MAP^*(P)$ measured during inflation (FIG. 4A) have a tight, well-correlated distribution compared to those measured during deflation (FIG. 4B). This indicates that a calibration determined from a pressure-dependent measurement made during inflation is likely more accurate than one made during deflation. Without being bound by any theory, this discrepancy may be due an inflation-based pressure-dependent measurement that gradually reduces blood flow in an underlying artery until it is ultimately occluded. In contrast, a deflation-based measurement first fully occludes the artery, and then gradually reduces the occlusion as the cuff deflates. Dammed-up blood rapidly flows through the artery during this process. This increase in blood flow may cause turbulence and other complicated hemodynamic events that add variability to the PTT value. Such processes are likely not present during an inflation-based measurement.

[0074] In FIG. 4A, a linear fit to the values of PTT vs. $MAP^*(P)$, shown by the dashed line **130**, also fits the measurements of PTT vs. MAP. This indicates a calibration determined during the pressure-dependent measurement (triangles) can be used to accurately measure blood pressure values made during subsequent pressure-free measurements (squares). In FIG. 4B, the linear fit to the PTT vs. $MAP^*(P)$ values, shown by the dashed line **131**, does not accurately fit the measurements of PTT vs. MAP. This result is expected based on the variability of the PTT vs. $MAP^*(P)$ values, and

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indicates that this calibration has a relatively low accuracy compared to that made during inflation.

[0075] Use of Inflation-Based Oscillometry in the Composite Method

[0076] FIG. 5A illustrates the equivalency between inflation-based and deflation-based oscillometric blood pressure measurements. The top portion of the figure shows an unfiltered pressure waveform 139, measured during the pressure-dependent measurement, which includes periods of both inflation 137 and deflation 138. Pulses associated with the patient's heartbeat couple into a bladder in the cuff during both periods. Following a measurement, the pressure waveform 139 is processed using a 0.5→5.0 Hz digital bandpass filter to remove the slowly varying baseline. As shown in FIG. 5B, filtering results in a time-dependent pressure waveform 140 featuring separate pulse trains measured during both inflation and deflation; the time-dependent amplitudes of each pulse in the train are characterized by a Gaussian envelope. Pressure corresponding to the peak of the Gaussian envelope represents a direct measurement of mean arterial pressure. Diastolic blood pressure, which is measured indirectly, corresponds to a pressure less than mean arterial pressure when the ratio of the envelope to its maximum value is 0.72. This ratio, along with the ratio for systolic blood pressure (typically 0.55), is described in more detail in U.S. Pat. No. 6,719,703, the contents of which are incorporated herein by reference.

[0077] As described above, oscillometry is used during the indexing measurement to determine SYS_{INDEX} , DIA_{INDEX} , and MAP_{INDEX} . These values are extracted from a 'processed pressure waveform', shown in FIG. 6, which is determined from a pressure waveform collected during inflation as shown in FIG. 5. The pressure waveform indicates how amplitude of each heartbeat-induced pulse in the time-dependent pressure waveform varies with pressure applied by the cuff. During a measurement, a pressure sensor in the pneumatic system shown in FIG. 24A collects and digitizes the pressure waveform, which is then processed as described below to determine the processed pressure waveform, and ultimately SYS_{INDEX} , DIA_{INDEX} , and MAP_{INDEX} .

[0078] A two-stage digital filtering algorithm determines the processed pressure waveform. This involves first filtering the raw pressure waveform with a bandpass filter that, in typical applications, features a second-order infinite impulse response (IIR) function that passes frequencies between 0.5→7.5 Hz. The second-order IIR filter transfer function typically takes the form:

$$H_F(z) = \frac{b_0 z^2 + b_1 z + b_2}{z^2 + a_1 z + a_2} \quad (3)$$

and is implemented as a difference equation, as shown in Equation (4):

$$y[n] = b_0 x[n] + b_1 x[n-1] + b_2 x[n-2] - a_1 y[n-1] - a_2 y[n-2] \quad (4)$$

[0079] Input to the first stage of the IIR filter is the raw, unprocessed pressure waveform, similar to that shown in FIG. 5A. Processing with the first stage yields the pulse waveform, similar to that shown in FIG. 5B. In order to remove any phase distortion, the IIR filter is executed in both the forward and reverse directions. The reverse filtering step doubles the effective order of the filter, and cancels out any phase distortion introduced by the forward filtering opera-

tion. The reverse filtering step is implemented by executing the standard IIR difference equation (i.e. Equation (4)), performing a time-reversal on the outputted data, and then executing the same IIR difference equation. While effective in removing phase distortion, such additional steps require an extra difference computation which cannot be performed in real-time on a stream of data. This, in turn, increases power consumption in the wrist-worn transceiver, and thus shortens battery life.

[0080] As the cuff inflates around the patient's arm, perturbations due to patient motion, kinks in the cuff, rapid speed changes in the pump's motor, and other artifacts may affect the pressure waveform. Such perturbations are typically non-physiological, and thus should be removed to minimize their influence on the oscillometric envelope. Their impact can be minimized by a number of different techniques. These include setting certain, noise-containing sections of the pressure waveform equal to zero and removing any data points in the waveform that show a rapid change in value over a relatively short period of time. After the potential artifacts have been removed, the pulse waveform is rectified to prepare for the second filtering operation. Rectification involves transforming the waveform into a new waveform (P_{RECT}) that features only positive components. P_{RECT} is calculated from the original pressure waveform (P_{ORIG}) using Equation (5), below:

$$P_{RECT}(i) = \begin{cases} -1 \times P_{ORIG}(i) & \text{if } P_{ORIG}(i) < 0 \\ P_{ORIG}(i) & \text{otherwise} \end{cases} \quad (5)$$

[0081] To complete the second phase of the filtering process, the rectified waveform is filtered with a digital low-pass filter based on an IIR filter. The low-pass filter typically only passes components less than 0.2 Hz to yield a smooth, low-frequency envelope indicating the pulse amplitude variation, as shown in FIG. 6. This waveform represents the 'processed pressure waveform', and can then be analyzed with techniques borrowed from oscillometry to determine the patient's 'indexed' blood pressure values, i.e. SYS_{INDEX} , DIA_{INDEX} , and MAP_{INDEX} . Specifically, the peak of the processed pressure waveform corresponds to MAP_{INDEX} . This is because, during oscillometry, the maximum amplitude of the heartbeat-induced pulses occurs when the brachial transmural pressure is zero. This takes place when the pressure inside the cuff equals MAP in the brachial artery. Oscillometry thus represents a direct measure of MAP . Both SYS_{INDEX} and DIA_{INDEX} are calculated using an empirical model based on amplitudes of the waveform on both sides of MAP_{INDEX} , as indicated in FIG. 6. During an actual measurement, the peak of the processed pressure waveform is determined using standard means, such as calculating a mathematical derivative and determining a positive-to-negative zero-point crossing. SYS_{INDEX} and DIA_{INDEX} are then determined from features of the waveform located, respectively, at higher and lower pressures compared to MAP_{INDEX} . Referring again to FIG. 6, SYS_{INDEX} , for example, is the pressure corresponding to 0.55 times the peak amplitude on the right-hand (high-pressure) side of the processed pressure waveform. DIA_{INDEX} is the pressure corresponding to 0.70 times the peak amplitude on the left-hand (low pressure) side of the waveform.

[0082] The above-described ratios (0.55 and 0.70) corresponding to SYS_{INDEX} and DIA_{INDEX} are typically deter-

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mined empirically using studies with a large and diverse patient population. They can vary with physiological properties associated with a given patient. For example, the ratios can vary depending on the patient's MAP, shape of the processed waveform, heart rate, biometric data (e.g. gender, height, weight, age), and other factors. A reference that describes the variation of ratios with the shape of the processed pressure waveform is described in the following reference, the contents of which are fully incorporated herein by reference: Amore et al., 'Effect of the shapes of the pulse amplitude oscillometric envelope and their characteristic ratios on the differences between auscultatory and oscillometric blood pressure measurements', *Blood Pressure Monitoring* 2007; 12:297-305. Once determined, the resultant values for MAP_{INDEX} , SYS_{INDEX} , and DIA_{INDEX} can be checked for accuracy using a variety of simple tests. For example, MAP_{INDEX} can be compared to the geometric MAP (MAP_{GEO}) determined from SYS_{INDEX} and DIA_{INDEX} using Equation (6), below. This test is based on the inherent relationship between MAP, SYS, and DIA, as described in the following reference, the contents of which are fully incorporated herein by reference: Chemla et al., 'Mean aortic pressure is the geometric mean of systolic and diastolic pressure in resting humans', *J Appl Physiol* 2005; 99:2278-2284.

$$|MAP_{DIFF}| > DIFF_{MAX}, \text{ where } MAP_{DIFF} = (MAP_{INDEX} - MAP_{GEO}) \quad (6)$$

[0083] In Equation (6) MAP_{GEO} is determined from the following equation:

$$MAP_{GEO} = \sqrt{(SYS_{INDEX} \times DIA_{INDEX})} \quad (7)$$

[0084] In embodiments, for example, $DIFF_{MAX}$ is equal to 13 mmHg. This means a measurement is rejected if the difference between MAP_{INDEX} and MAP_{GEO} is greater or less than 13 mmHg. Such a situation would occur, for example, if the processed pressure waveform was distorted by a motion-related artifact that occurred during the oscillometric measurement. When an oscillometric measurement is rejected, a NULL value is returned, and the body-worn monitor instructs the pneumatic system to re-inflate the cuff, and the measurement is repeated.

[0085] Once MAP_{INDEX} , SYS_{INDEX} , and DIA_{INDEX} are determined, the systolic and diastolic ratios (R_{SYS} and R_{DIA}) are calculated as described below in Equation (8):

$$R_{SYS} = SYS_{INDEX} / MAP_{INDEX} \quad (8)$$

$$R_{DIA} = DIA_{INDEX} / MAP_{INDEX}$$

[0086] These ratios may vary in a dynamic fashion according to other physiological parameters determined during a measurement, particularly heart rate. Such variation is described in the above-referenced journal article, entitled Chemla et al., 'Mean aortic pressure is the geometric mean of systolic and diastolic pressure in resting humans', *J Appl Physiol* 2005; 99:2278-2284, the contents of which have been previously incorporated by reference. For example, Equation (9), below, indicates how these ratios may vary with heart rate:

$$R_{SYS} = a \times HR \times SYS_{INDEX} / MAP_{INDEX} \quad (9)$$

$$R_{DIA} = b \times HR \times DIA_{INDEX} / MAP_{INDEX}$$

[0087] In Equation (9), the coefficients a and b are determined empirically, typically using studies on either humans or animals. For these studies blood pressure and heart rate

data are typically collected with a diverse group of patients undergoing a range of physiological conditions, and then analyzed. Note that the ratios shown in Equation (9) will only exhibit dynamic behavior if the patient's heart rate is variable.

[0088] As described above, the Composite Method can also include an intermediate pressure-dependent indexing measurement that determines systolic, diastolic, and means arterial pressures using an abbreviated applied pressure. In this case, to find systolic blood pressure, the algorithm can detect the amplitude of each pulse in the PPG waveform, and fit them to a variety of mathematical models to 'predict' and extrapolate exactly where the amplitude decreases to zero. For example, the algorithm can fit the last eight data points in FIG. 4B to a linear function. In this case knowledge of the patient's heart rate (e.g. frequency and rhythm), as determined from the ECG waveform, can enhance the accuracy of the prediction and provide a confidence indicator of the metric. The algorithm may take a mathematical derivative of the PPG waveform to eliminate any affects of the waveform's baseline. The above-described algorithms may then be used to predict disappearance of the pulse and thus the onset of systolic blood pressure.

[0089] During the intermediate pressure-dependent measurement, pressure is typically applied until just after mean arterial pressure is calculated as described above, and then terminated. At this point, the amplitude of the PPG waveform is typically in decline, and can be fit with the linear function to predict systolic blood pressure. Both systolic and mean arterial pressures are then used to determine diastolic pressure, as described above. The intermediate pressure-dependent measurement is typically performed, for example, every 4 hours in place of the regular pressure-dependent measurement.

[0090] Measuring PTT and Determining cNIBP with the Composite Method

[0091] Following indexing, cNIBP is determined on a beat-by-beat basis from PTT, which as indicated by the arrow 154 in FIG. 7A is determined from the time difference between features in the ECG and PPG waveforms. Specifically, PTT separates a sharply peaked QRS complex in the ECG waveform, indicated in the figure by the black circle 150, from the base of the PPG waveform, shown by the black circle 151. PTT typically varies inversely with blood pressure, i.e. a decrease in PTT indicates an increase in blood pressure. In theory, PTT is affected by blood pressure and a variety of other factors, such as arterial compliance, arterial size, vascular resistance, PEP, and LVET. For this reason, PTT, taken by itself, only indicates relative changes in blood pressure. But when combined with the above-mentioned indexing process, which estimates absolute blood pressure values and 'calibrates' for factors that affect PTT but not necessarily blood pressure, PTT can accurately monitor cNIBP. As described above, during a measurement the body-worn monitor measures PTT corresponding to every heartbeat for a given time period, typically lying between 20-60 seconds. During this time period, specific PTT values may be filtered out to remove erroneous values affected by artifacts, such as motion. For example, both average and standard deviation values can be calculated for a set of PTT values measured during the time period. The total number of PTT values will, of course, depend on the heart rate, and is typically between 15 and 60 for a 30-second measurement period. Values that differ from the average by more than one standard deviation can be assumed to be artificial, and thus removed from the

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calculation. At this point an average PTT value is then recalculated for the time period and used for the subsequent cNIBP calculation. Similar statistical processing techniques, such as those using numerical fitting, processing of Gaussian distributions, or digital filtering, can also be used to exclude PTT values estimated to be erroneous. Statistics are typically calculated for individual time periods. Alternatively, they may be calculated on a 'rolling basis' in which the time period is kept relatively large, but is sequentially updated, e.g., each second. This approach has the advantage that it can yield a 'fresh' blood pressure value at a relatively high frequency.

[0092] Referring again to FIG. 7A, PTT is typically calculated from the foot or 'onset' of the PPG waveform, indicated by the black circle 151, which indicates an arrival of the pressure pulse. Physically, the onset point 151 represents beginning of a volumetric increase in vasculature that lies underneath the thumb-worn sensor (294) shown in FIG. 24A. A pressure pulse launched by the patient's beating heart propagates along their vasculature, driving blood into it and causing a temporary expansion upon its arrival. The expansion increases optical absorption according to the Beer-Lambert law. Radiation that passes through the expanding vasculature is detected by a photodetector, resulting in a time-dependent PPG. Technically, the waveform shown in FIG. 7A is an inverted version of the 'true' PPG, as the increase in optical absorption reduces the amount of radiation and resulting signal detected by the photodetector within the thumb-worn sensor.

[0093] Alternatively, PTT can be calculated from other regions of the waveform, such as a point along its rising edge or its peak. Timing associated with these regions, however, may be affected by properties of the underlying vasculature (such as elasticity) that are decoupled from blood pressure. For this reason they are less desirable than the waveform's onset. In embodiments, however, they may be used to augment calculation of PTT. For example, as shown by the middle trace of FIG. 7B, the first derivative of the PPG yields a well-defined peak indicating the maximum slope of the PPG that can easily be detected with a computer algorithm. For unusually noisy PPGs, this fiducial marker may be used to help locate the PPG's onset, or may be processed with the onset to generate an 'average' PTT value for the waveform. Other features of the waveform, such as its maximum value, may also be processed in a similar manner.

[0094] In other embodiments, multiple PPGs measured during a SpO2 measurement may be processed to generate a single PTT. Such a measurement is described in the following co-pending patent application, the contents of which are fully incorporated herein by reference: 'BODY-WORN PULSE OXIMETER' (U.S. Ser. No. 12/559,403; filed Sep. 14, 2009). As described in this reference, during a typical SpO2 measurement PPGs are measured with both red (~660 nm) and infrared (~905 nm) wavelengths. These PPGs have similar features, but may be affected by motion-related noise, as well as other artifacts such as ambient light, in different ways. The onset of each PPG can thus be independently detected, and then averaged together to generate a single PTT. Other techniques for processing multiple PPGs to determine a single PTT are described below, particularly with reference to FIGS. 15-17.

[0095] FIG. 7B shows one method for determining the onset of a PPG waveform, indicated in the top portion of the figure by the black circle 152. Before processing, the PPG waveform is typically filtered with a digital finite impulse

response (FIR) filter, which removes high-frequency noise from the waveform prior to processing. Such noise is typically due to electrical or mechanical sources. Removing it is critical for effective signal processing, as it is amplified after taking a numerical derivative. This reduces a signal-to-noise ratio of the derivatized waveform, which in turn may lead to erroneous measurements. The first derivative of the PPG waveform peaks at a point corresponding to the maximum rise time of the unprocessed PPG waveform. This point, shown in the middle trace of FIG. 7B, typically follows the onset point by 20-100 ms. As shown as the bottom trace in the figure, the second derivative of the waveform peaks at a point corresponding to the onset. This is indicated in the figure by the black circle 153, and correlates with the PPG onset as indicated by the dashed line 155. Such a peak is characterized by a well-defined positive-to-negative slope change, and is relatively easy to detect with a standard computer algorithm. Once detected, this value is processed along with the ECG QRS to determine PTT.

[0096] Once determined, PTT is used along with blood pressures determined during indexing with inflation-based oscillometry (MAP_{INDEX} , SYS_{INDEX} , and DIA_{INDEX}) and a patient-specific slope (m_{cNIBP}) to determine a MAP component of cNIBP (MAP_{cNIBP}). Equation (10), below, shows the relationship between these parameters:

$$MAP_{cNIBP} = (m_{cNIBP} \times PTT) - (m_{cNIBP} \times PTT_{INDEX}) + MAP_{INDEX} \quad (10)$$

where PTT_{INDEX} is the PTT value determined at the start of the indexing process. SYS_{cNIBP} and DIA_{cNIBP} are then determined from MAP_{cNIBP} for each heartbeat using the relationships described in Equation (11), below:

$$SYS_{cNIBP} = MAP_{cNIBP} \times R_{SYS} \quad (11)$$

$$DIA_{cNIBP} = MAP_{cNIBP} \times R_{DIA}$$

where R_{SYS} and R_{DIA} are described above in Equation (8) and, optionally, Equation (9).

[0097] In other embodiments, the blood pressure ratios shown in Equation (11) can be adjusted depending on other signals measured from the patient, such as shapes associated with the PPG and ECG waveforms. For example, a relationship between the PPG waveform shape and SYS , DIA , and MAP that can be used in this embodiment is described in U.S. Pat. No. 5,269,310, the contents of which are incorporated herein by reference. In other embodiments, unique patient-specific slopes and y-intercepts relating SYS , DIA , and MAP to PTT, similar to that shown for MAP_{cNIBP} in Equation (10), can be determined beforehand and used to independently calculate these blood pressures. In still other embodiments, 'default' slopes calculated beforehand from large groups of patients can be used in place of the patient-specific slopes. A default slope would be used, for example, if it were difficult to determine a patient-specific slope as described above because of a motion-related artifact or a problem associated with the pneumatic system.

[0098] Implementation of the Composite Method

[0099] FIG. 8 shows one possible sequence 178 of the Composite Method's pressure-dependent (steps 182a), pressure-free (steps 181a, 181b, 181c), and intermediate pressure-dependent (steps 182b, 182c) measurements for a patient undergoing an extended hospital stay. During the stay, a medical professional applies the body-worn monitor, optical sensor, and chest electrodes to the patient (step 180). This takes about one minute. The medical professional may also

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collect biometric information from the patient, such as their age, weight, height, gender, ethnicity, and whether they are on blood pressure medications, and enter these into the monitor using a graphical user interface and touch panel. This information is then communicated wirelessly to the remote monitor. Going forward, a microprocessor within the body-worn monitor's electronics module first initiates a pressure-free measurement (step 181a) for about one minute, wherein the body-worn monitor collects PPG and ECG waveforms from the patient, determines their heart rate and PTT, and can estimate their blood pressure. In the absence of an absolute blood pressure measurement from the Composite Method's pressure-dependent measurement, the microprocessor may use PTT and the patient's biometric information to estimate blood pressure, as is described in the following co-pending patent application, the contents of which have been previously incorporated herein by reference: DEVICE AND METHOD FOR DETERMINING BLOOD PRESSURE USING 'HYBRID' PULSE TRANSIT TIME MEASUREMENT (U.S. Ser. No. 60/943,464; filed Jun. 12, 2007); and, VITAL SIGN MONITOR FOR CUFFLESSLY MEASURING BLOOD PRESSURE USING A PULSE TRANSIT TIME CORRECTED FOR VASCULAR INDEX (U.S. Ser. No. 60/943,523; filed Jun. 12, 2007). This process typically determines systolic and diastolic blood pressure with an accuracy of about ± 10 -15 mmHg.

[0100] The initial, approximate value for the patient's blood pressure and heart rate determined during the first pressure-free measurement (step 181a) can then be used to set certain parameters during the following first pressure-dependent indexing measurement (step 182a). Knowledge of these parameters may ultimately increase the accuracy of the first pressure-dependent measurement (step 182a). Such parameters, for example, may include inflation time and rate, fitting parameters for determining the time-dependent increase in PTT and the time-dependent decrease in PPG waveform amplitude during the pressure-dependent measurement. Of particular importance is an accurate value of the patient's heart rate determined during the first pressure-free measurement (step 181a). Since both PTT and amplitude can only be measured from a pulse induced by a heartbeat, the algorithm can process heart rate and use it in the fitting process to accurately determine the pressure at which the PPG waveform amplitude crosses zero.

[0101] Using parameters such as heart rate and initial estimated blood pressure, the first pressure-dependent indexing measurement (step 182a) determines a relationship between PTT and blood pressure as described above. This measurement takes about 40 seconds, and may occur automatically (e.g., after about 1 minute), or may be driven by the medical professional (e.g., through a button press). The microprocessor then uses this relationship and a measured value of PTT to determine blood pressure during the following pressure-free measurement (step 181b). This measurement step typically proceeds for a well-defined period of time (e.g., 4-8 hours), during which it continuously determines blood pressure. Typically, to conserve battery life, the body-worn monitor averages PTT values over a 10-20 second period, and makes one blood pressure measurement every 3-5 minutes.

[0102] The microprocessor may also perform a pre-programmed or automated intermediate pressure-dependent measurement (step 182b) to correct any drift in the blood pressure measurement. As described above, this step involves only partial inflation of the bladder within the cuff, during

which the microprocessor fits the pressure-dependent decrease in the amplitude of pulses in the PPG waveform to a linear model. This measurement takes less time than the first pressure-dependent measurement (step 182a), and accurately determines blood pressure values that are used going forward in a second pressure-free measurement (step 181c). As before, this measurement typically continues for a well-defined period of time. At a later time, if the patient experiences a sudden change in other vital signs (e.g., respiratory rate, heart rate, body temperature), the microprocessor may analyze this condition and initiate another pressure-dependent blood pressure measurement (step 182c) to most accurately determine cNIBP.

[0103] Correlation Between cNIBP Measurements Made with the Composite Method and a Femoral A-Line

[0104] cNIBP measurements made according to the Composite Method correlate particularly well to blood pressure continuously measured from a patient's femoral artery using an arterial catheter, or 'A-line'. Correlating cNIBP measurements to this reference standard represents an improvement over many previous studies that relate PTT to blood pressure measured with an A-line inserted a patient's radial artery, a location that is commonly used in hospital settings, such as the ICU. Such studies are described, for example, in the following references, the contents of which are incorporated herein by reference: Payne et al., 'Pulse transit time measured from the ECG: an unreliable marker of beat-to-beat blood pressure', *J Appl Physiol* 2006; 100:136-141. One reason for poor agreement between blood pressure measured with PTT and a radial A-line involves a phenomenon called 'pulse pressure amplification' wherein a patient's blood pressure gradually increases along their arterial tree as the diameter of the artery supporting the pressure is decreased, as described in the following reference, the contents of which are fully incorporated herein by reference: Verbeke et al., 'Non-invasive assessment of local pulse pressure: importance of brachial to radial pressure amplification', *Hypertension* 2005; 46:244-248. To summarize, gradual tapering that commonly occurs from the brachial to radial arteries can have little effect on DIA or MAP, but can increase pulse pressure (defined as SYS-DIA) by as much as 10 mmHg or more. For the measurement described herein, this means blood pressure measured at the radial artery is typically higher than that measured at the brachial artery. And this phenomenon can reduce correlation between blood pressure measured using the Composite Method and a radial A-line, as the Composite Method is calibrated using an indexing measurement made at the patient's brachial artery. In contrast, blood pressure at the femoral artery is typically similar to that measured at the brachial artery. The following references, the contents of which are fully incorporated herein by reference, describe the strong correlations between blood pressures measured at these different sites: Park et al., 'Direct blood pressure measurements in brachial and femoral arteries in children', *Circulation* 1970; XL1:231-237; and Pascarelli et al., 'Comparison of leg and arm blood pressures in aortic insufficiency: an appraisal of Hill's Sign', *Brit Med J* 1965; 2:73-75. Without being bound to any theory, the strong correlation between brachial and femoral pressure may occur because both arteries are large, close to the patient's heart, and support pressures indicative of the patient's core. The relatively large diameters of these arteries may additionally minimize the influence of the arterial wall on the internal pressure. In contrast, the radial artery is a significantly smaller artery with a relatively high

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surface-to-volume ratio, which tends to increase blood pressure. This is one reason, for example, that SYS measured at a patient's extremities (using e.g. a finger cuff) is typically higher than their core blood pressure.

[0105] FIG. 9 shows a graphic that this indicates this effect. In the figure, a patient 200 undergoing a cNIBP measurement has an indexing measurement performed at their brachial artery, as indicated by the black circle 201. As described above, the indexing measurement yields oscillometric blood pressures and a patient-specific relationship between PTT and blood pressure. These parameters are specific to the brachial artery, but also agree well with those determined at other large arteries, such as the femoral arteries. PTT indicates a transit time describing the delay associated with a pressure pulse launched by the patient's heartbeat and arriving at the optical sensor, which is typically located on their thumb. The pathway associated with the transit time is shown by the line 203 in the figure. During a correlation study, a reference measurement is typically made using an A-line inserted into the patient's femoral artery, as shown by the black circle 202. Correlation between these two measurements is typically very good, presumably because the large nature of both the femoral and brachial arteries limits the influence of pulse pressure amplification, particularly on SYS values.

[0106] In some cases, however, instantaneous blood pressure measured at both the femoral and brachial arteries do not agree. According to the above-described references (particularly Pascarelli et al.), differences between these pressures may be as large as 20 mmHg, and typically result from cardiac problems such as blockages or 'aortic insufficiencies'. Differences tend to be larger for unhealthy patients. They typically affect the average difference, or bias, between the cNIBP measurement described herein and the reference A-line measurement, but have little effect on the correlation between these two measurements. If a blood pressure study with a large number of patients is performed, differences between femoral and brachial blood pressures may also contribute to an inter-subject (i.e. 'between subject') error, typically characterized by a standard deviation. Such errors can be compensated for during the study with a calibration approach involving measuring brachial blood pressure with a reference technique, such as manual auscultation, and using this value to estimate the patient's inherent brachial-femoral blood pressure difference. In this case a calibration measurement indicates if disagreement between cNIBP and femoral A-line measurements are caused by device-to-device measurement differences, or human physiology.

[0107] Clinical Results

[0108] FIG. 10 shows a typical, time-dependent cNIBP measurement according to the Composite Method, and how this yields a SYS value that correlates better with blood pressure measured at the femoral artery compared to the radial artery. For this study, each of the above-mentioned blood pressures (cNIBP, femoral, radial) were measured simultaneously. All measurements were performed in the ICU of a hospital based in San Diego, Calif. Both femoral and radial pressures were measured every second with in-dwelling A-line catheters connected to a conventional vital sign monitor (Philips Intellivue). cNIBP was simultaneously measured and averaged over a 40-second period with a device similar to that shown in FIG. 24. Data from the Philips Intellivue monitor was sent through a serial connection to a specialized data-acquisition computer running a custom software application, while data from the cNIBP measurement

was sent through a wireless connection (using Bluetooth) to the same computer. Once collected by the data-acquisition computer, blood pressure values from the A-lines were averaged over an identical 40-second period, and then compared to the cNIBP data. All data for these experiments were collected over a 4-hour period with a single indexing measurement performed at the beginning of the study.

[0109] As shown in FIG. 10, cNIBP measurements (black trace) agree fairly well with corresponding measurements from the femoral A-line (dark gray trace) over the entire 4-hour period, with both the STDEV (5.7 mmHg) and BIAS (-2.4 mmHg) between paired values of these measurements falling well below the FDA's standards for blood pressure monitoring devices (STDEV <8 mmHg; BIAS <+/-5 mmHg). These standards are described in detail in the AAMI SP-10:2002, a standards document that outlines requirements for blood pressure monitoring devices. As described above, particularly with reference to FIG. 9, the cNIBP measurement is indexed with an oscillometric measurement made at the subject's brachial artery, a relatively large vessel that, like the femoral artery, supports a pressure that is representative of core blood pressure. Larger arteries near the patient's core, unlike smaller arteries at the extremities, typically do not facilitate artificially elevated blood pressures due to pulse pressure amplification. Blood pressure measured at the subject's relatively small radial artery (light gray trace) is elevated compared to both cNIBP and femoral blood pressures. Additionally, blood pressure at the radial artery tends to be relatively volatile compared to the other blood pressures. Without being bound to any theory, this too may also be due to pulse pressure amplification. Correlation between radial blood pressure and cNIBP is notably worse than that between cNIBP and femoral blood pressure, with both STDEV (9.3 mmHg) and BIAS (-12.8 mmHg) for the paired values falling outside of the FDA's guidelines. Data similar to that shown in FIG. 10 was collected from 23 subjects in a recent study using the device and method according to the invention.

[0110] FIG. 11 shows typical correlation between both SYS and DIA measured with the Composite Method and a femoral A-line. Data were collected in the same manner described above. Blood pressure was measured over a 4-hour period with only a single indexing measurement performed at the beginning of the study. cNIBP measurements for both SYS and DIA in FIG. 11, like that described above in FIG. 10, correlate well with pressures measured at the femoral artery, and comfortably meet the guidelines required by the FDA. FIG. 12, for example, shows blood pressure correlations (shown as standard deviation) from a cohort of 23 subjects measured in two different ICUs using both the Composite Method and a femoral A-line. All subjects were measured under essentially identical conditions to those described above. The figure shows a histogram that graphs standard deviation values between the two measurements for both SYS (dark gray bars) and DIA (light gray bars). The histogram indicates that, for all measurements collected from 23 subjects, only a single measurement (for SYS) falls outside the FDA's guidelines of 8 mmHg for STDEV. All other measurements are comfortably within this limit, and as expected show Gaussian-type distributions, with the distributions peaked near 3 and 4 mmHg for, respectively, SYS and DIA.

[0111] FIG. 13 shows the collective, intra-subject statistics determined for all 23 subjects for the above-described study. Statistics were determined using two independent techniques. The first technique, called 'analysis of variance' or

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'ANOVA', tests statistical variance for a set of repeated measures, like those used in the ICU study. ANOVA models for STDEV and BIAS are commonly used for analysis of data collected in clinical trials, like the one described herein. The second technique shown in FIG. 13 simply calculates the STDEV and BIAS for each subject in the study over the 4-hour measurement period, and then calculates the average of each of these parameters for the group. In general, this 'AVERAGE' analysis is less formal than an ANOVA analysis; it is used herein simply to provide a secondary analysis of the data.

[0112] As shown in FIG. 13, for the 23 subjects measured in this study, the intra-subject cNIBP measurements analyzed with both ANOVA and the AVERAGE analysis comfortably meet the FDA's requirements for both intra-subject BIAS and STDEV. For SYS, the intra-subject BIAS was calculated at 2.1 and 2.6 mmHg using, respectively, the ANOVA and AVERAGE analyses. Intra-subject STDEVs for SYS were calculated as 5.9 and 4.8 mmHg using the two techniques. For DIA, the intra-subject BIAS was calculated at 1.9 and 2.7 mmHg using, respectively, the ANOVA and AVERAGE analyses. Intra-subject STDEVs for DIA were calculated as 3.6 and 3.0 mmHg using the two techniques. In all cases, these statistics comfortably meet the FDA's guidelines for BIAS ($\leq \pm 5$ mmHg) and STDEV (≤ 8 mmHg), as outlined in the above-referenced AAMI SP-10:2002 reference standard.

[0113] FIG. 14 shows a table describing drift calculated for the 4-hour measurement period for 22 of the above-mentioned subjects (one subject was excluded because their measurement period was less than 4 hours). Additionally, a follow-on study with 6 subjects investigated drift over an 8-hour measurement period. For this study, a single indexing measurement was performed at the beginning of the measurement, and all subsequent measurements made over the 8-hour period were based exclusively on PTT. In both cases, drift was calculated using a linear regression technique included in a SAS Statistical Analysis Software Package. More specifically, drift was estimated in a repeated-measures mixed-effects general linear model using the TROC MIXED model in SAS. This model includes a 'fixed time effect' model to estimate the drift. As shown in the table, drift over the 4-hour period is relatively small (-0.07 and -0.01 mmHg/hour for, respectively, SYS and DIA), essentially within the error of the cNIBP measurement, and clinically insignificant. Drift for the 8-hour measurement period (-0.4 and -0.3 for, respectively, SYS and DIA) is slightly larger, although still within the error of the cNIBP measurement and likely clinically insignificant.

[0114] Drift is an important parameter for characterizing the cNIBP measurement, as it essentially indicates how frequently the Composite Method must be indexed. Drift is generally attributed to a change (either gradual or rapid) in the subject's cardiovascular properties that builds in after an indexing measurement. Such a change, for example, may be attributed to a change in vascular compliance, tone, pre-injection period (PEP), left ventricular ejection time (LVET), or arterial dilation. Ideally, an indexing measurement would be performed at most once every 8-hours, as this time period corresponds with a typical nursing shift. In this case, the nurse would index a patient at the beginning of the shift using the oscillometric approach described herein. As shown in FIG. 24, the indexing measurement typically takes less than 1 minute, and is performed with a cuff-based system that seamlessly integrates with the body-worn monitor used to make

the cNIBP measurements. After the indexing measurement, the cuff-based system is removed, and all follow-on cNIBP measurements are made cufflessly using only the ECG and PPG waveforms. At the 8-hour mark, the cuff-based system is reapplied to the patient, and the process is repeated. At this point the subject's arterial properties and value for SYS, DIA, and MAP are recalculated and used for all subsequent measurements that take place over the next 8 hours.

[0115] Effect of Motion on PPG and ECG Waveforms

[0116] Motion is a parameter that confounds measurement of all vital signs, and is particularly detrimental to optical measurements, such as those used in the Composite Method for cNIBP and pulse oximetry. For this reason it is important for the body-worn monitor to both recognize motion and, ideally, accurately determine the vital sign in its presence.

[0117] In a preferred embodiment, motion, posture, arm height, and activity level are determined from a patient by analyzing signals from three separate accelerometers integrated within the body-worn monitor. As shown in detail in FIG. 24, the accelerometers are integrated into the monitor's cabling and wrist-worn transceiver. Each measures three unique signals, each corresponding to the x, y, and z-axes of the body portion to which the accelerometer attaches. These signals are then processed with a series of algorithms, some of which are described in the following patent application, the contents of which are incorporated herein by reference: BODY-WORN VITAL SIGN MONITOR WITH SYSTEM FOR DETECTING AND ANALYZING MOTION (U.S. Ser. No. 12/469,094; filed May 20, 2009). A software framework generates a series of alarms/alerts based on threshold values that are either preset or determined in real time. The framework additionally includes a series of 'heuristic' rules that take the patient's activity state and motion into account, and process the vital signs accordingly. These rules, for example, indicate that a walking patient is likely breathing and has a regular heart rate, even if their motion-corrupted vital signs suggest otherwise. They are described in the following patent application, the contents of which are fully incorporated herein by reference: BODY-WORN MONITOR FEATURING ALARM SYSTEM THAT PROCESSES A PATIENT'S MOTION AND VITAL SIGNS (U.S. Ser. No. 12/469,182; filed May 20, 2009).

[0118] Measuring cNIBP During Motion

[0119] A variety of techniques can be used to remove motion artifacts from signals used to measure cNIBP, and particularly from the PPG waveform used in this measurement. For example, as described in detail below, a single thumb-worn sensor measures PPG waveforms with both red (~ 660 nm) and infrared (~ 905 nm) wavelengths to determine an SpO₂ measurement. Both PPGs waveforms are affected by motion, and can be collectively processed to remove motion artifacts to some degree. FIGS. 15-17 show results from this analysis. FIG. 15, for example, shows both IR (top trace) and RED (second trace) PPG waveforms measured as a function of time over a 60-second period. Both waveforms were simultaneously measured from the base of the patient's thumb using the sensor shown in FIG. 24. Each waveform features a series of pulses, similar to those shown in FIG. 7A, indicating a heartbeat-induced volumetric expansion in vasculature lying beneath the optical sensor located at the base of the patient's thumb. A period of motion beginning at about 40 seconds and lasting for about 10 seconds, and indicated with the box 220, corrupts both PPG waveforms to the point that a clear, well-defined pulse cannot be measured. In this case,

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motion consisted of rapid, large-scale motion of the patient's hand. The third trace in FIG. 15 shows the IR PPG waveform divided by the RED PPG waveform. Division reduces the relative amplitudes between motion artifacts shown in the box 220 and the heartbeat-induced pulses shown before and after this period, although not to the point that individual pulses can be determined during the period of motion. However, processing the divided signal with a digital bandpass filter yields a resultant signal shown in the bottom trace that has clear, well-defined pulses. In this case, the bandpass filter was implemented with an IIR response function with a band-pass ranging from 0.001→5 Hz. The resultant pulses, while still somewhat distorted by motion, may be used to determine a PTT and consequently a cNIBP measurement.

[0120] FIG. 16 shows a similar result. In this case, however, the RED PPG is subtracted from the IR PPG to yield the third trace. Here, the relative amplitude between heartbeat-induced pulses (shown before and after the box 222 indicating the period of motion) and the motion-affected signal is slightly larger than that resulting from division, as shown in FIG. 15, indicating that subtraction may be preferable to division for this algorithm. The resultant signal is processed with the same digital bandpass filter described above to yield the bottom trace in the figure. Again, such processing yields pulses with reasonable signal-to-noise ratios, even in the presence of substantial motion. Following this processing, pulses within the resultant PPG may be used to determine cNIBP, as described above.

[0121] Importantly, collective processing of both the RED and IR PPGs signals, combined with digital filtering, is significantly more effective at removing motion artifacts than simply filtering the signals by themselves. FIG. 17, for example, shows both the IR (top trace) and RED (second trace) PPG waveforms following processing with the same digital bandpass filter used to generate the data shown in FIGS. 15 and 16. In this case the period of motion is indicated by the box 225. Even after processing, these waveforms lack any clear, well-defined pulses during the period of motion. This indicates that filtering a single waveform is likely not adequate for removing motion-induced artifacts. Such waveforms, for example, would not be suitable for PTT-based cNIBP measurements. In contrast, the third trace in FIG. 17 shows the filtered PPG waveforms after the RED PPG is subtracted from the IR PPG. In this case no additional filtering is performed. The resultant waveform, like those shown in the bottom traces of FIGS. 15 and 16, features well-defined pulses that can be subsequently processed to determine PTT-based cNIBP.

[0122] FIGS. 18 and 19 show an alternative method for collectively using both ECG 250a,b and PPG 252a,b waveforms to measure cNIBP in the presence of motion. This method is based on the fundamental principal that ECG waveforms 250a,b, which rely on electrical signals measured from the patient's chest, are relatively immune from motion artifacts, making it relatively easy to measure HR values therefrom even when large-scale motion is present. In contrast, PPG waveforms 252a,b measured with optical means are relatively susceptible to motion artifacts. Similar to the method described above, it is the collective processing of these signals that yields accurate cNIBP measurement even when the patient is moving.

[0123] Collective processing of both HR and PTT determined from ECG and PPG waveforms yields a methodology for approximating PTT during periods of motion. This algorithm features analyzing the patient's current HR and a preceding array of paired values of HR/PTT using a continuous linear fitting approach, and then using these parameters

resulting from the fit to estimate PTT. The theory behind the algorithm is as follows. Referring to FIG. 18, when no motion is present both the ECG 250a and PPG 252a waveforms are relatively noise-free. In this case cNIBP is determined from PTT (i.e. $cNIBP = F[PTT]$) using the Composite Method, which processes the time separating the QRS complex within the ECG 250a and the base of the PPG waveform 252a. When motion is present, the ECG waveform 250b remains relatively noise-free, but the PPG waveform 252b is corrupted by noise. In this case, cNIBP is calculated from HR (i.e. $cNIBP = F[HR]$) using a real-time, evolving relationship between these two parameters. As indicated by the graph in the lower portion of FIG. 18, HR and PTT have little correlation when evaluated over long periods of time (e.g. 10 minutes or longer), but can have reasonable (or in fact very good) correlations when evaluated over very short periods of time (e.g. less than 2 minutes). Such correlation is indicated by the box 253. This is because cardiac output, which relates HR and cNIBP, is typically constant for these short periods. FIG. 19 illustrates this principal in more detail. As shown by the boxes 230, 232, a relationship between HR and PTT can be determined by analyzing a preceding array of paired HR/PTT values, collected when the patient is not moving, with a simple linear regression model. These arrays, shown in the figure as $[HR/PTT]$, and $[HR/PTT]_{i+1}$, are collected over a period ΔT , which is typically between 20 and 60 seconds. The linear model used to fit the array returns a corresponding slope ($M_{HR/PTT,i}$), y-intercept ($B_{HR/PTT,i}$), and correlation value ($r^2_{HR/PTT,i}$). At a subsequent time, indicated by the arrows 231, 233, the patient begins to move and parameters from the linear model can be used along with a current, motion-immune HR value to estimate a value of PTT called an 'effective' PTT (PTT*). Specifically, PTT* is calculated using Equation (12) below, and then used in place of PTT to calculate cNIBP as described above.

$$PTT^* = HR \times M_{HR/PTT,i} + B_{HR+PTT,i} \quad (12)$$

[0124] The relationship between HR and PTT determined with the linear model is most accurate when the HR and PTT data points are collected immediately prior to the period of motion. If patient motion continues, then this model can be used along with HR for a period of time of up to 5 minutes to calculate cNIBP values. If patient motion persists past this period, then cNIBP cannot typically be accurately calculated, and this methodology should not be used. Typically this approach works best if correlation between HR and PTT, as indicated by $r^2_{HR/PTT,i}$, is relatively strong. In preferred embodiments, $r^2_{HR/PTT,i}$ is greater than about 0.5 for the algorithm to be implemented. If $r^2_{HR/PTT,i}$ is less than this value the algorithm is not implemented, and a blood pressure value is assumed to be corrupted by motion, and thus not reported.

[0125] FIGS. 20A,B and 21A,B indicate the efficacy of this approach. FIGS. 20A and 21A show time-dependent traces of SYS, measured with a femoral A-line, and a 'reconstructed' SYS determined using Equation (11). These graphs were generated using data measured during the 23-subject ICU study, described above. FIGS. 20B and 21B plot the same data in FIGS. 20A and 21A in a different way, showing a point-to-point correlation between SYS measured with the femoral arterial line and 'reconstructed' SYS measured with the method according to the invention. As is clear from these graphs, reconstructing SYS values using this approach yields better agreement and higher correlation when the subject's blood pressure undergoes only small amounts of volatility. For example, FIGS. 20A,B show the 'best' results from the group of 23 subjects. Here, the subject's blood pressure is relatively stable, and the reconstructed SYS agrees extremely

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well with SYS measured using the femoral arterial line (STDEV=2.0 mmHg; BIAS=0.2 mmHg). FIGS. 21A,B show data from a subject with highly volatile blood pressure. This case represents the 'worst' agreement for the 23 subjects, likely because the volatility in cNIBP also results in a corresponding volatility in cardiac output. This, in turn, makes it more difficult to accurately reconstruct the subject's cNIBP, and results in slightly worse correlation (STDEV=15.8 mmHg; BIAS=0.6 mmHg) between arterial line and reconstructed SYS.

[0126] Processing Accelerometer Waveforms to Determine Posture

[0127] In addition to motion, a patient's posture can influence how the above-described system generates alarms/alerts from cNIBP and other vital signs. For example, the alarms/alerts related to cNIBP may vary depending on whether the patient is lying down or standing up. FIG. 22 indicates how the body-worn monitor can determine motion-related parameters (e.g. degree of motion, posture, and activity level) from a patient 110 using time-dependent accelerometer waveforms continuously generated from the three accelerometers 262, 263, 264 worn, respectively, on the patient's chest, bicep, and wrist. The height of the patient's arm can affect the cNIBP measurement, as blood pressure can vary significantly due to hydrostatic forces induced by changes in arm height. Moreover, this phenomenon can be detected and exploited to calibrate the cNIBP measurement, as described in detail in the above-referenced patent application, the contents of which have been previously incorporated by reference: BODY-WORN VITAL SIGN MONITOR WITH SYSTEM FOR DETECTING AND ANALYZING MOTION (U.S. Ser. No. 12/469,094; filed May 20, 2009). As described in this document, arm height can be determined using DC signals from the accelerometers 263, 264 disposed, respectively, on the patient's bicep and wrist. Posture, in contrast, can be exclusively determined by the accelerometer 262 worn on the patient's chest. An algorithm operating on the wrist-worn transceiver extracts DC values from waveforms measured from this accelerometer and processes them with an algorithm described below to determine posture.

[0128] Specifically, torso posture is determined for a patient 260 using angles determined between the measured gravitational vector and the axes of a torso coordinate space 261. The axes of this space 261 are defined in a three-dimensional Euclidean space where \vec{R}_{CV} is the vertical axis, \vec{R}_{CH} is the horizontal axis, and \vec{R}_{CN} is the normal axis. These axes must be identified relative to a 'chest accelerometer coordinate space' before the patient's posture can be determined.

[0129] The first step in determining a patient's posture is to identify alignment of \vec{R}_{CV} in the chest accelerometer coordinate space. This can be determined in either of two approaches. In the first approach, \vec{R}_{CV} is assumed based on a typical alignment of the body-worn monitor relative to the patient. During a manufacturing process, these parameters are then preprogrammed into firmware operating on the wrist-worn transceiver. In this procedure it is assumed that accelerometers within the body-worn monitor are applied to each patient with essentially the same configuration. In the second approach, \vec{R}_{CV} is identified on a patient-specific basis. Here, an algorithm operating on the wrist-worn transceiver prompts the patient (using, e.g., video instruction operating on the wrist-worn transceiver, or audio instructions

transmitted through a speaker) to assume a known position with respect to gravity (e.g., standing upright with arms pointed straight down). The algorithm then calculates \vec{R}_{CV} from DC values corresponding to the x, y, and z axes of the chest accelerometer while the patient is in this position. This case, however, still requires knowledge of which arm (left or right) the monitor is worn on, as the chest accelerometer coordinate space can be rotated by 180 degrees depending on this orientation. A medical professional applying the monitor can enter this information using the GUI, described above. This potential for dual-arm attachment requires a set of two pre-determined vertical and normal vectors which are interchangeable depending on the monitor's location. Instead of manually entering this information, the arm on which the monitor is worn can be easily determined following attachment using measured values from the chest accelerometer values, with the assumption that \vec{R}_{CV} is not orthogonal to the gravity vector.

[0130] The second step in the procedure is to identify the alignment of \vec{R}_{CN} in the chest accelerometer coordinate space. The monitor determines this vector in the same way it determines \vec{R}_{CV} using one of two approaches. In the first approach the monitor assumes a typical alignment of the chest-worn accelerometer on the patient. In the second approach, the alignment is identified by prompting the patient to assume a known position with respect to gravity. The monitor then calculates \vec{R}_{CN} from the DC values of the time-dependent accelerometer waveform.

[0131] The third step in the procedure is to identify the alignment of \vec{R}_{CH} in the chest accelerometer coordinate space. This vector is typically determined from the vector cross product of \vec{R}_{CV} and \vec{R}_{CN} , or it can be assumed based on the typical alignment of the accelerometer on the patient, as described above.

[0132] A patient's posture is determined using the coordinate system described above and in FIG. 22, along with a gravitational vector \vec{R}_G that extends normal from the patient's chest. The angle between \vec{R}_{CV} and \vec{R}_G is given by equation (13):

$$\theta_{VG}[n] = \arccos\left(\frac{\vec{R}_G[n] \cdot \vec{R}_{CV}}{\|\vec{R}_G[n]\| \|\vec{R}_{CV}\|}\right) \quad (13)$$

where the dot product of the two vectors is defined as:

$$\vec{R}_G[n] \cdot \vec{R}_{CV} = (y_{Cx}[n] \times r_{CVx}) + (y_{Cy}[n] \times r_{CVy}) + (y_{Cz}[n] \times r_{CVz}) \quad (14)$$

[0133] The definition of the norms of \vec{R}_G and \vec{R}_{CV} are given by equations (15) and (16):

$$\|\vec{R}_G[n]\| = \sqrt{(y_{Cx}[n])^2 + (y_{Cy}[n])^2 + (y_{Cz}[n])^2} \quad (15)$$

$$\|\vec{R}_{CV}\| = \sqrt{(r_{CVx})^2 + (r_{CVy})^2 + (r_{CVz})^2} \quad (16)$$

[0134] As indicated in equation (5), the monitor compares the vertical angle θ_{VG} to a threshold angle to determine

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whether the patient is vertical (i.e. standing upright) or lying down:

$$\text{if } \theta_{VG} \leq 45^\circ \text{ then Torso State}=0, \text{ the patient is upright} \quad (17)$$

[0135] If the condition in equation (17) is met the patient is assumed to be upright, and their torso state, which is a numerical value equated to the patient's posture, is equal to 0. The patient is assumed to be lying down if the condition in equation (17) is not met, i.e. $\theta_{VG} > 45^\circ$ degrees. Their lying position is then determined from angles separating the two remaining vectors, as defined below.

[0136] The angle θ_{NG} between \vec{R}_{CN} and \vec{R}_G determines if the patient is lying in the supine position (chest up), prone position (chest down), or on their side. Based on either an assumed orientation or a patient-specific calibration procedure, as described above, the alignment of \vec{R}_{CN} is given by equation (18), where i, j, k represent the unit vectors of the x, y, and z axes of the chest accelerometer coordinate space respectively:

$$\vec{R}_{CN} = r_{CNx}\hat{i} + r_{CNy}\hat{j} + r_{CNz}\hat{k} \quad (18)$$

[0137] The angle between \vec{R}_{CN} and \vec{R}_G determined from DC values extracted from the chest accelerometer waveform is given by equation (19):

$$\theta_{NG}[n] = \arccos\left(\frac{\vec{R}_G[n] \cdot \vec{R}_{CN}}{\|\vec{R}_G[n]\| \|\vec{R}_{CN}\|}\right) \quad (19)$$

[0138] The body-worn monitor determines the normal angle θ_{NG} and then compares it to a set of predetermined threshold angles to determine which position the patient is lying in, as shown in equation (20):

$$\text{if } \theta_{NG} \leq 35^\circ \text{ then Torso State}=1, \text{ the patient is supine} \quad (20)$$

$$\text{if } \theta_{NG} \geq 135^\circ \text{ then Torso State}=2, \text{ the patient is prone}$$

[0139] If the conditions in equation (20) are not met then the patient is assumed to be lying on their side. Whether they are lying on their right or left side is determined from the angle calculated between the horizontal torso vector and measured gravitational vectors, as described above.

[0140] The alignment of \vec{R}_{CH} is determined using either an assumed orientation, or from the vector cross-product of \vec{R}_{CV} and \vec{R}_{CN} as given by equation (21), where i, j, k represent the unit vectors of the x, y, and z axes of the accelerometer coordinate space respectively. Note that the orientation of the calculated vector is dependent on the order of the vectors in the operation. The order below defines the horizontal axis as positive towards the right side of the patient's body.

$$\vec{R}_{CH} = r_{CVx}\hat{i} + r_{CVy}\hat{j} + r_{CVz}\hat{k} = \vec{R}_{CV} \times \vec{R}_{CN} \quad (21)$$

The angle θ_{HG} between \vec{R}_{CH} and \vec{R}_G is determined using equation (22):

$$\theta_{HG}[n] = \arccos\left(\frac{\vec{R}_G[n] \cdot \vec{R}_{CH}}{\|\vec{R}_G[n]\| \|\vec{R}_{CH}\|}\right) \quad (22)$$

[0141] The monitor compares this angle to a set of predetermined threshold angles to determine if the patient is lying on their right or left side, as given by equation (23):

$$\begin{aligned} &\text{if } \theta_{HG} \geq 90^\circ \text{ then Torso State}=3, \text{ the patient is on their right side} \\ &\text{if } \theta_{HG} < 90^\circ \text{ then Torso State}=4, \text{ the patient is on their left side} \end{aligned} \quad (23)$$

[0142] Table 1 describes each of the above-described postures, along with a corresponding numerical torso state used to render, e.g., a particular icon on a remote computer:

TABLE 1

postures and their corresponding torso states	
Posture	Torso State
standing upright	0
supine: lying on back	1
prone: lying on chest	2
lying on right side	3
lying on left side	4
undetermined posture	5

[0143] FIGS. 23A and 23B show, respectively, graphs of time-dependent accelerometer waveforms measured along the x, y, and z-axes (FIG. 23A), and the torso states (i.e. postures; FIG. 23B) determined from these waveforms for a moving patient, as described above. As the patient moves, the DC values of the accelerometer waveforms measured by the chest accelerometer vary accordingly, as shown in FIG. 23A. The body-worn monitor processes these values as described

above to continually determine \vec{R}_G and the various quantized torso states for the patient, as shown in FIG. 23B. The torso states yield the patient's posture as defined in Table 1. For this study the patient rapidly alternated between standing, lying on their back, chest, right side, and left side within a time period of about 160 seconds. As described above, different alarm/alert conditions (e.g. threshold values) for vital signs can be assigned to each of these postures, or the specific posture itself may result in an alarm/alert. Additionally, the time-dependent properties of the graph can be analyzed (e.g. changes in the torso states can be counted) to determine, for example, how often the patient moves in their hospital bed. This number can then be equated to various metrics, such as a 'bed sore index' indicating a patient that is so stationary in their bed that lesions may result. Such a state could then be used to trigger an alarm/alert to the supervising medical professional.

[0144] Body-Worn Monitor for Measuring cNIBP

[0145] FIGS. 24A and 24B show how the body-worn monitor 300 described above attaches to a patient 270 to measure cNIBP and other vital signs. A detailed description of this monitor is provided by the following co-pending patent application, the contents of which are incorporated herein by reference: BODY-WORN VITAL SIGN MONITOR (U.S. Ser. No. 12/560,087; filed Sep. 15, 2009). These figures show two configurations of the system: FIG. 24A shows the system used during the indexing portion of the Composite Method, and includes a pneumatic, cuff-based system 285, while FIG. 24B shows the system used for subsequent cNIBP measurements. The indexing measurement typically takes about 60

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seconds, and is typically performed once every 4 hours. Once the indexing measurement is complete the cuff-based system **285** is typically removed from the patient. The remainder of the time the monitor **300** performs the cNIBP measurements.

[0146] The body-worn monitor **300** features a wrist-worn transceiver **272**, described in more detail in FIG. 25, featuring a touch panel interface **273** that displays cNIBP values and other vital signs. A wrist strap **290** affixes the transceiver **272** to the patient's wrist like a conventional wristwatch. A flexible cable **292** connects the transceiver **272** to a pulse oximeter probe **294** that wraps around the base of the patient's thumb. During a measurement, the probe **294** generates a time-dependent PPG waveform which is processed along with an ECG to measure cNIBP and SpO₂. This provides an accurate representation of blood pressure in the central regions of the patient's body, as described above.

[0147] To determine accelerometer waveforms the body-worn monitor **300** features three separate accelerometers located at different portions on the patient's arm and chest. The first accelerometer is surface-mounted on a circuit board in the wrist-worn transceiver **272** and measures signals associated with movement of the patient's wrist. As described above, this motion can also be indicative of that originating from the patient's fingers, which will affect the SpO₂ measurement. The second accelerometer is included in a small bulkhead portion **296** included along the span of the cable **282**. During a measurement, a small piece of disposable tape, similar in size to a conventional bandaid, affixes the bulkhead portion **296** to the patient's arm. In this way the bulkhead portion **296** serves two purposes: 1) it measures a time-dependent accelerometer waveform from the mid-portion of the patient's arm, thereby allowing their posture and arm height to be determined as described in detail above; and 2) it secures the cable **282** to the patient's arm to increase comfort and performance of the body-worn monitor **300**, particularly when the patient is ambulatory. The third accelerometer is mounted in a bulkhead component **274** that connects through cables **280a-c** to ECG electrodes **278a-c**. These signals are then digitized, transmitted through the cable **282** to the wrist-worn transceiver **272**, where they are processed with an algorithm as described above to determine respiration rate, as described in the following co-pending patent applications, the contents of which are incorporated herein by reference: BODY-WORN MONITOR FOR MEASURING RESPIRATION RATE (U.S. Ser. No. 12/559,442; filed Sep. 14, 2009).

[0148] The cuff-based module **285** features a pneumatic system **276** that includes a pump, valve, pressure fittings, pressure sensor, analog-to-digital converter, microcontroller, and rechargeable Li:ion battery. During an indexing measurement, the pneumatic system **276** inflates a disposable cuff **284** and performs two measurements according to the Composite Method: 1) it performs an inflation-based measurement of oscillometry to determine values for SYS_{INDEX}, DIA_{INDEX}, and MAP_{INDEX}; and 2) it determines a patient-specific slope describing the relationship between PTT and MAP. These measurements are described in detail in the above-referenced patent application entitled: 'VITAL SIGN MONITOR FOR MEASURING BLOOD PRESSURE USING OPTICAL, ELECTRICAL, AND PRESSURE WAVEFORMS' (U.S. Ser. No. 12/138,194; filed Jun. 12, 2008), the contents of which have been previously incorporated herein by reference.

[0149] The cuff **284** within the cuff-based pneumatic system **285** is typically disposable and features an internal, airtight bladder that wraps around the patient's bicep to deliver

a uniform pressure field. During the indexing measurement, pressure values are digitized by the internal analog-to-digital converter, and sent through a cable **286** according to a CAN protocol, along with SYS_{INDEX}, DIA_{INDEX}, and MAP_{INDEX} to the wrist-worn transceiver **272** for processing as described above. Once the cuff-based measurement is complete, the cuff-based module **285** is removed from the patient's arm and the cable **286** is disconnected from the wrist-worn transceiver **272**. cNIBP is then determined using PTT, as described in detail above.

[0150] To determine an ECG, the body-worn monitor **300** features a small-scale, three-lead ECG circuit integrated directly into the bulkhead **274** that terminates an ECG cable **282**. The ECG circuit features an integrated circuit that collects electrical signals from three chest-worn ECG electrodes **278a-c** connected through cables **280a-c**. As described above, the ECG electrodes **278a-c** are typically disposed in a conventional Einthoven's Triangle configuration which is a triangle-like orientation of the electrodes **278a-c** on the patient's chest that features three unique ECG vectors. From these electrical signals the ECG circuit determines up to three ECG waveforms, which are digitized using an analog-to-digital converter mounted proximal to the ECG circuit, and sent through the cable **282** to the wrist-worn transceiver **272** according to the CAN protocol. There, the ECG and PPG waveforms are processed to determine the patient's blood pressure. Heart rate and respiration are determined directly from the ECG waveform using known algorithms, such impedance pneumography, as well as those described above. The cable bulkhead **274** also includes an accelerometer that measures motion associated with the patient's chest as described above.

[0151] As described above, there are several advantages of digitizing ECG and accelerometer waveforms prior to transmitting them through the cable **282**. First, a single transmission line in the cable **282** can transmit multiple digital waveforms, each generated by different sensors. This includes multiple ECG waveforms (corresponding, e.g., to vectors associated with three, five, and twelve-lead ECG systems) from the ECG circuit mounted in the bulkhead **274**, along with waveforms associated with the x, y, and z-axes of accelerometers mounted in the bulkheads **274**, **296**. More sophisticated ECG circuits (e.g. five and twelve-lead systems) can plug into the wrist-worn transceiver to replace the three-lead system shown in FIGS. 24A and 24B.

[0152] FIG. 25 shows a close-up view of the wrist-worn transceiver **272**. As described above, it attaches to the patient's wrist using a flexible strap **290** which threads through two D-ring openings in a plastic housing **306**. The transceiver **272** features a touch panel display **320** that renders a GUI **273** which is altered depending on the viewer (typically the patient or a medical professional). Specifically, the transceiver **272** includes a small-scale infrared barcode scanner **302** that, during use, can scan a barcode worn on a badge of a medical professional. The barcode indicates to the transceiver's software that, for example, a nurse or doctor is viewing the user interface. In response, the GUI **273** displays vital sign data and other medical diagnostic information appropriate for medical professionals. Using this GUI **273**, the nurse or doctor, for example, can view the vital sign information, set alarm parameters, and enter information about the patient (e.g. their demographic information, medication, or medical condition). The nurse can press a button on the GUI **273** indicating that these operations are complete. At

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this point, the display 320 renders an interface that is more appropriate to the patient, such as time of day and battery power.

[0153] The transceiver 272 features three CAN connectors 304a-c on the side of its upper portion, each which supports the CAN protocol and wiring schematics, and relays digitized data to the internal CPU. Digital signals that pass through the CAN connectors include a header that indicates the specific signal (e.g. ECG, ACC, or pressure waveform from the cuff-based module) and the sensor from which the signal originated. This allows the CPU to easily interpret signals that arrive through the CAN connectors 304a-c, such as those described above corresponding to ECG waveforms, and means that these connectors are not associated with a specific cable. Any cable connecting to the transceiver can be plugged into any connector 304a-c. As shown in FIG. 24A, the first connector 304a receives the cable 282 that transports a digitized ECG waveform determined from the ECG circuit and electrodes, and digitized accelerometer waveforms measured by accelerometers in the cable bulkhead 274 and the bulkhead portion 296 associated with the ECG cable 282.

[0154] The second CAN connector 304b shown in FIG. 25 receives the cable 286 that connects to the pneumatic cuff-based system 285 used for the pressure-dependent indexing measurement (shown in FIG. 24A). This connector 304b receives a time-dependent pressure waveform delivered by the pneumatic system 285 to the patient's arm, along with values for SYS_{INDEX} , DIA_{INDEX} , and MAP_{INDEX} values determined during the indexing measurement. The cable 286 unplugs from the connector 304b once the indexing measurement is complete, and is plugged back in after approximately four hours for another indexing measurement.

[0155] The final CAN connector 304c can be used for an ancillary device, e.g. a glucometer, infusion pump, body-worn insulin pump, ventilator, or et-CO2 measurement system. As described above, digital information generated by these systems will include a header that indicates their origin so that the CPU can process them accordingly.

[0156] The transceiver includes a speaker 301 that allows a medical professional to communicate with the patient using a voice over Internet protocol (VOIP). For example, using the speaker 301 the medical professional could query the patient from a central nursing station or mobile phone connected to a wireless, Internet-based network within the hospital. Or the medical professional could wear a separate transceiver similar to the shown in FIG. 25, and use this as a communication device. In this application, the transceiver 272 worn by the patient functions much like a conventional cellular telephone or 'walkie talkie': it can be used for voice communications with the medical professional and can additionally relay information describing the patient's vital signs and motion. The speaker can also enunciate pre-programmed messages to the patient, such as those used to calibrate the chest-worn accelerometers for a posture calculation, as described above.

[0157] Multi-Pixel Sensors for Measuring PPG Waveforms in the Presence of Motion

[0158] As described above and shown in FIG. 24A, the thumb-worn sensor typically used in the body-worn monitor features a photodetector with a single-pixel light-detecting region. Typically this pixel has an area of 2-4 mm². During the Composite Method, the photodetector measures a PPG waveform, which is collectively processed with the ECG waveform to determine cNIBP. Alternatively, as shown in FIGS. 26-29, an optical sensor 351 featuring a multi-pixel

detector 354 can be used in place of a single-pixel detector to measure a PPG waveform. Such a detector 354 may be particularly effective at detecting signals when a patient is in motion.

[0159] The multi-pixel sensor 351 features a soft, flexible substrate 352 coated on its perimeter with an adhesive 356 designed to adhere to a patient's skin. As shown in FIG. 26, for optimal results the sensor 351 is adhered to the forehead of a patient 350, and connects through a cable 352 to a controller 353. In this embodiment, the controller 353 and cable 352 are similar, respectively, to the wrist-worn transceiver 273 and cable 292 shown in FIG. 24A. Experiments indicate that the forehead is the ideal sensor location for this alternative embodiment, presumably because tissue supporting underlying vasculature is relatively thin and buttressed on its inner side with bone from the patient's skull. This physiology minimizes motion between the sensor 351 and arteries in the forehead that can cause artifacts in the PPG. Additionally, presence of the skull limits the compressibility of the thin, underlying tissue, which in turn minimizes motion-induced flow of both blood and interstitial fluids within the tissue. These factors, particularly when coupled with the forehead's large available measurement area relatively small degree of motion, make this location ideal for the sensor 351.

[0160] The sensor 351 typically features a square footprint and includes four dual-wavelength LEDs 353a-d positioned in each of its corners. Each LED 353a-d emits both red and infrared optical wavelengths, as described above. An adjustable voltage bias supplied to each LED determines its emitted wavelength. During a measurement, the substrate 352 attaches to the patient's forehead with the adhesive 356, allowing the LEDs 353a-d to deliver a relatively uniform optical field to the tissue underneath. The optical field is partially absorbed by pulsating blood in the underlying vasculature according to the Beer-Lambert law, as described above. This modulates the optical field, which is then detected in a reflection-mode geometry by the multi-pixel detector 354. Each pixel element in the detector 354 typically has an area of 1-2 mm², and generates a unique, analog electrical field which propagates through a series of electrical interconnects 355 to an electrical system 357 featuring a multichannel analog-to-digital converter (A/D) coupled to a circuit for multiplexing and demultiplexing (MUX) the resulting digital signals. These components digitize the analog signals from each pixel element and process them to form a single PPG waveform, similar to that shown in FIG. 7A.

[0161] FIGS. 28A,B and 29A,B indicate how the multi-pixel sensor 351a,b (FIGS. 29A,B) may be superior at detecting PPG waveforms during motion when compared to a conventional single-pixel detector 385a,b (FIGS. 28A,B). Blood is a viscoelastic fluid, and during motion will ebb and flow in a patient's arterial system according to Newtonian physics. This affect, informally referred to herein as 'blood sloshing', can be characterized by time-dependent properties (e.g. rise and fall times) that are similar in their frequency makeup to an actual pulse in a PPG waveform. This is why, for example, motion-induced artifacts shown in the waveforms in FIGS. 15 and 16 look similar to the actual pulses in the PPG. Blood sloshing causes a bolus of blood 390a,b to move in and out of the region measured with a single-pixel detector 387a,b shown in FIGS. 28A,B. The single detector 387a,b has no ability to track the time-dependent dynamics of the bolus of blood 390a,b as it moves across the detector field. The bolus 390a moves into the detector field at time t₀, propagates

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across the field, and finally moves out at time $t_0 + \Delta t$. Because it cannot be isolated, the bolus 390a,b results in an artifact in the PPG waveform that is difficult, if not impossible, to remove with conventional means, such as a digital filter.

[0162] In contrast, FIGS. 29A,B show how a multi-pixel detector 351a,b can track the bolus of blood 380a,b as it moves across the detector area. This allows it to be isolated and removed from the PPG waveform using the multiplexing/demultiplexing circuitry 357 described with reference to FIG. 27. In this case, for example, the bolus 380a,b moves across a diagonal line in the detector field; only pixels lying along this line will yield signals affected by the motion-related artifact. These signals will show different behavior than conventional PPG waveforms, which will be detected by pixels in the upper left-hand and lower right-hand portions of the multi-array detector 354a,b. Once detected, signals from each pixel can be processed with a variety of signal-processing techniques, such as those used to process video images, to deconvolute artifacts arising from the bolus. Ultimately this can yield a relatively noise-free PPG waveform, which can then be processed with the Composite Method to determine cNIBP.

[0163] High-Level Algorithm for Measuring All Vital Signs

[0164] FIG. 30 provides a flow chart that shows a high-level algorithm 399, including the Composite Method, used to monitor vital signs from a hospitalized patient. The initiation phase (step 400) of the algorithm 399 begins with collection of time-dependent PPG, ECG, and accelerometer waveforms using analog and digital circuitry within the body-worn monitor. PPG waveforms are measured using an optical sensor attached to the patient's thumb, while ECG waveforms are measured with a series of electrodes (typically three or five) attached to the patient's chest. Three accelerometers, integrated within the body-worn monitor's cabling and wrist-worn transceiver, each measure three digital accelerometer waveforms corresponding to an x, y, or z-axis. Once collected, the PPG and accelerometer waveforms are digitally filtered (step 401) so that time-dependent properties can be extracted and processed as described in detail above. The pressure waveform, which is generated during an indexing measurement using a pneumatic system and cuff wrapped around the patient's bicep, is measured during inflation and processed using oscillometry to determine SYS_{INDEX} , DIA_{INDEX} , and MAP_{INDEX} values (step 402). Alternatively, SYS_{INDEX} can be determined directly by processing the PPG in the presence of applied pressure during the indexing measurement, as described above with reference to FIG. 8 (step 403). PTT is measured as a function of applied pressure during the indexing measurement, and is processed to determine a personal, patient-specific slope (step 404). Motion can complicate measurement of the above-described parameters, and is determined by processing time-dependent signals from the three accelerometers attached to the patient and connected to the body-worn monitor. These signals are collected and processed to determine the degree of motion-based signal corruption (step 405), and to additionally determine the patient's posture and activity level (step 407). If motion is determined to be present, cNIBP can be estimated using the read-through motion algorithm described above with reference to FIGS. 18 and 19 (step 408).

[0165] When minimal or no motion is present, the patient-specific slope, along with blood pressure values determined with oscillometry during the indexing measurements, are

used with PTT values measured from the ECG and PPG waveforms to determine cNIBP (step 410). PPG waveforms measured with both red and infrared waveforms are additionally processed to determine SpO₂, as described above, using modified calculation parameters tailored for the base of the thumb (step 411).

[0166] The body-worn monitor makes the above-described measurements for PTT-based cNIBP by collecting data for 20-second periods, and then processing these data with a variety of statistical averaging techniques as described above. Additionally, algorithms that process ECG and accelerometer waveforms using adaptive filtering can determine respiration rate, as described in the following patent application, the contents of which have been previously incorporated herein by reference: BODY-WORN MONITOR FOR MEASURING RESPIRATION RATE (U.S. Ser. No. 12/559,442; filed Sep. 14, 2009) (step 412). Heart rate and temperature are then determined as described in the following patent application, the contents of which have been already incorporated herein by reference: BODY-WORN VITAL SIGN MONITOR (U.S. Ser. No. 12/560,087; filed Sep. 15, 2009) (step 413).

[0167] All the vital signs described above are typically calculated with a technique for rolling averages that updates them every second. Every 4-8 hours the indexing measurement is repeated, either with a complete inflation-based measurement (step 402), or one based on partial inflation (step 403) as described above.

Other Embodiments

[0168] In addition to those methods described above, a number of additional methods can be used to calculate blood pressure from the PPG and ECG waveforms. These are described in the following co-pending patent applications, the contents of which are incorporated herein by reference: 1) CUFFLESS BLOOD-PRESSURE MONITOR AND ACCOMPANYING WIRELESS, INTERNET-BASED SYSTEM (U.S. Ser. No. 10/709,015; filed Apr. 7, 2004); 2) CUFFLESS SYSTEM FOR MEASURING BLOOD PRESSURE (U.S. Ser. No. 10/709,014; filed Apr. 7, 2004); 3) CUFFLESS BLOOD PRESSURE MONITOR AND ACCOMPANYING WEB SERVICES INTERFACE (U.S. Ser. No. 10/810,237; filed Mar. 26, 2004); 4) VITAL SIGN MONITOR FOR ATHLETIC APPLICATIONS (U.S. Ser. No. _____; filed Sep. 13, 2004); 5) CUFFLESS BLOOD PRESSURE MONITOR AND ACCOMPANYING WIRELESS MOBILE DEVICE (U.S. Ser. No. 10/967,511; filed Oct. 18, 2004); 6) BLOOD PRESSURE MONITORING DEVICE FEATURING A CALIBRATION-BASED ANALYSIS (U.S. Ser. No. 10/967,610; filed Oct. 18, 2004); 7) PERSONAL COMPUTER-BASED VITAL SIGN MONITOR (U.S. Ser. No. 10/906,342; filed Feb. 15, 2005); 8) PATCH SENSOR FOR MEASURING BLOOD PRESSURE WITHOUT A CUFF (U.S. Ser. No. 10/906,315; filed Feb. 14, 2005); 9) PATCH SENSOR FOR MEASURING VITAL SIGNS (U.S. Ser. No. 11/160,957; filed Jul. 18, 2005); 10) WIRELESS, INTERNET-BASED SYSTEM FOR MEASURING VITAL SIGNS FROM A PLURALITY OF PATIENTS IN A HOSPITAL OR MEDICAL CLINIC (U.S. Ser. No. 11/162,719; filed Sep. 9, 2005); 11) HAND-HELD MONITOR FOR MEASURING VITAL SIGNS (U.S. Ser. No. 11/162,742; filed Sep. 21, 2005); 12) CHEST STRAP FOR MEASURING VITAL SIGNS (U.S. Ser. No. 11/306,243; filed Dec. 20, 2005); 13) SYSTEM FOR MEASURING VITAL SIGNS USING AN OPTICAL MODULE FEATUR-

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ING A GREEN LIGHT SOURCE (U.S. Ser. No. 11/307,375; filed Feb. 3, 2006); 14) BILATERAL DEVICE, SYSTEM AND METHOD FOR MONITORING VITAL SIGNS (U.S. Ser. No. 11/420,281; filed May 25, 2006); 15) SYSTEM FOR MEASURING VITAL SIGNS USING BILATERAL PULSE TRANSIT TIME (U.S. Ser. No. 11/420,652; filed May 26, 2006); 16) BLOOD PRESSURE MONITOR (U.S. Ser. No. 11/530,076; filed Sep. 8, 2006); 17) TWO-PART PATCH SENSOR FOR MONITORING VITAL SIGNS (U.S. Ser. No. 11/558,538; filed Nov. 10, 2006); and, 18) MONITOR FOR MEASURING VITAL SIGNS AND RENDERING VIDEO IMAGES (U.S. Ser. No. 11/682,177; filed Mar. 5, 2007).

[0169] Other embodiments are also within the scope of the invention. For example, other measurement techniques, such as conventional oscillometry measured during deflation, can be used to determine SYS for the above-described algorithms. Additionally, processing components and sensors for measuring SpO₂ similar to those described above can be modified and worn on other portions of the patient's body. For example, sensors with finger-ring configurations can be worn on fingers other than the thumb. Or they can be modified to attach to other conventional sites for measuring SpO₂, such as the ear, forehead, and bridge of the nose. In these embodiments the processing component can be worn in places other than the wrist, such as around the neck (and supported, e.g., by a lanyard) or on the patient's waist (supported, e.g., by a clip that attaches to the patient's belt). In still other embodiments the probe and processing component are integrated into a single unit.

[0170] In other embodiments, a set of body-worn monitors can continuously monitor a group of patients, wherein each patient in the group wears a body-worn monitor similar to those described herein. Additionally, each body-worn monitor can be augmented with a location sensor. The location sensor includes a wireless component and a location-processing component that receives a signal from the wireless component and processes it to determine a physical location of the patient. A processing component (similar to that described above) determines from the time-dependent waveforms at least one vital sign, one motion parameter, and an alarm parameter calculated from the combination of this information. A wireless transceiver transmits the vital sign, motion parameter, location of the patient, and alarm parameter through a wireless system. A remote computer system featuring a display and an interface to the wireless system receives the information and displays it on a user interface for each patient in the group.

[0171] In embodiments, the interface rendered on the display at the central nursing station features a field that displays a map corresponding to an area with multiple sections. Each section corresponds to the location of the patient and includes, e.g., the patient's vital signs, motion parameter, and alarm parameter. For example, the field can display a map corresponding to an area of a hospital (e.g. a hospital bay or emergency room), with each section corresponding to a specific bed, chair, or general location in the area. Typically the display renders graphical icons corresponding to the motion and alarm parameters for each patient in the group. In other embodiments, the body-worn monitor includes a graphical display that renders these parameters directly on the patient.

[0172] Typically the location sensor and the wireless transceiver operate on a common wireless system, e.g. a wireless system based on 802.11, 802.15.4, or cellular protocols. In

this case a location is determined by processing the wireless signal with one or more algorithms known in the art. These include, for example, triangulating signals received from at least three different base stations, or simply estimating a location based on signal strength and proximity to a particular base station. In still other embodiments the location sensor includes a conventional global positioning system (GPS).

[0173] The body-worn monitor can include a first voice interface, and the remote computer can include a second voice interface that integrates with the first voice interface. The location sensor, wireless transceiver, and first and second voice interfaces can all operate on a common wireless system, such as one of the above-described systems based on 802.11 or cellular protocols. The remote computer, for example, can be a monitor that is essentially identical to the monitor worn by the patient, and can be carried or worn by a medical professional. In this case the monitor associated with the medical professional features a GUI wherein the user can select to display information (e.g. vital signs, location, and alarms) corresponding to a particular patient. This monitor can also include a voice interface so the medical professional can communicate directly with the patient.

[0174] In other embodiments, a variety of software configurations can be run on the body-worn monitor to give it a PDA-like functionality. These include, for example, Micro C OS®, Linux®, Microsoft Windows®, embOS, VxWorks, SymbianOS, QNX, OSE, BSD and its variants, FreeDOS, FreeRTOS, LynxOS, or eCOS and other embedded operating systems. The monitor can also run a software configuration that allows it to receive and send voice calls, text messages, or video streams received through the Internet or from the nation-wide wireless network it connects to. The barcode scanner described with reference to FIG. 25 can also be used to capture patient or medical professional identification information, or other such labeling. This information, for example, can be used to communicate with a patient in a hospital or at home. In other embodiments, the device can connect to an Internet-accessible website to download content, e.g., calibrations, software updates, text messages, and information describing medications, from an associated website. As described above, the device can connect to the website using both wired (e.g., CAN) or wireless (e.g., short or long-range wireless transceivers) means. In still other embodiments, 'alert' values corresponding to vital signs and the pager or cell phone number of a caregiver can be programmed into the device using its graphical user interface. If a patient's vital signs meet an alert criteria, software on the device can send a wireless 'page' to the caregiver, thereby alerting them to the patient's condition. For additional patient safety, a confirmation scheme can be implemented that alerts other individuals or systems until acknowledgment of the alert is received.

[0175] Still other embodiments are within the scope of the following claims.

What is claimed is:

1. A method for monitoring a blood pressure value from a patient, comprising:

- (a) applying a variable pressure to the patient's arm using a pressure-delivery system;
- (b) detecting a time-dependent pressure waveform representing the pressure applied to the patient's arm;
- (c) detecting a first time-dependent waveform comprising a first feature induced by the patient's heartbeat with a first sensor configured to attach to the patient;

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- (d) detecting a second time-dependent waveform comprising a second feature induced by the patient's heartbeat with a second sensor configured to attach to the patient;
 - (e) determining a pulse transit time from a separation in time between the first feature and the second feature;
 - (f) determining a variation in the pulse transit time as a function of the pressure applied to the patient's arm;
 - (g) processing the variation in pulse transit time to determine a relationship between pulse transit time and blood pressure;
 - (h) digitally filtering a portion of the time-dependent pressure waveform to determine a processed pressure waveform;
 - (i) analyzing the processed pressure waveform to determine values for systolic blood pressure, diastolic blood pressure, and mean arterial pressure; and
 - (j) analyzing a pulse transit time, the relationship between pulse transit time and blood pressure, and blood pressure values determined from the processed pressure waveform to determine a blood pressure value when no pressure is applied to the patient's arm with the pressure delivery system.
2. A method for monitoring a blood pressure value from a patient, comprising:
- (a) applying a variable pressure to the patient's arm using a pressure-delivery system;
 - (b) detecting a time-dependent pressure waveform representing the pressure applied to the patient's arm during inflation of the pressure-delivery system;
 - (c) detecting a first time-dependent waveform comprising a first feature induced by the patient's heartbeat with a first sensor configured to attach to the patient;
 - (d) detecting a second time-dependent waveform comprising a second feature induced by the patient's heartbeat with a second sensor configured to attach to the patient;
 - (e) determining a pulse transit time from a separation in time between the first feature and the second feature;
 - (f) determining a variation in the pulse transit time as a function of the pressure applied to the patient's arm during inflation of the pressure-delivery system;
 - (g) processing the variation in pulse transit time to determine a relationship between pulse transit time and blood pressure;
 - (h) digitally filtering a portion of the time-dependent pressure waveform measured during inflation to determine a processed pressure waveform;
 - (i) analyzing the processed pressure waveform to determine values for systolic blood pressure, diastolic blood pressure, and mean arterial pressure; and
 - (j) analyzing a pulse transit time, the relationship between pulse transit time and blood pressure, and blood pressure values determined from the processed pressure waveform to determine a blood pressure value when no pressure is applied to the patient's arm with the pressure delivery system.
3. A method for monitoring a blood pressure value from a patient, comprising:
- (a) detecting a time-dependent pressure waveform representing pressure applied to the patient's arm during inflation of a pressure-delivery system;
 - (b) determining a pulse transit time between a first feature of a first time-dependent waveform and a second feature of a second time-dependent waveform, both the first and second waveforms measured from the patient;
 - (c) digitally filtering a portion of the time-dependent pressure waveform to determine a processed pressure waveform measured during inflation; and
 - (d) analyzing a pulse transit time and a calibration determined from a relationship between pulse transit time and blood pressure determined from parameters measured during inflation to determine a blood pressure value after inflation.
4. A method for monitoring a blood pressure value from a patient, comprising:
- (a) detecting a time-dependent pressure waveform representing pressure applied to the patient's arm during inflation of a pressure-delivery system;
 - (b) determining a pulse transit time between a first feature of a first time-dependent waveform and a second feature of a second time-dependent waveform, both the first and second waveforms measured from the patient;
 - (c) digitally filtering a portion of the time-dependent pressure waveform to determine a processed pressure waveform measured during inflation; and
 - (d) analyzing a pulse transit time and a calibration determined from a relationship between pulse transit time and blood pressure determined from parameters measured during inflation to determine a blood pressure value after inflation.
5. The method of claim 1, wherein step (g) further comprises processing the variation in pulse transit time to determine a relationship between pulse transit time and mean arterial pressure.
6. The method of claim 5, wherein step (g) further comprises processing the variation in pulse transit time with a mathematical model that estimates an effective mean arterial pressure in the patient's arm that varies with pressure applied by the pressure-delivery system.
7. The method of claim 6, wherein the effective mean arterial pressure is the difference between the mean arterial pressure determined during step (i) and a pressure-induced blood pressure change.
8. The method of claim 7, wherein the pressure-induced blood pressure change is defined by the following equation or a mathematical derivative thereof:
- $$\Delta MAP(P) = F \times (P_{\text{applied}} - DIA_{\text{INDEX}})$$
- where $\Delta MAP(P)$ is the pressure-induced blood pressure change, P_{applied} is pressure applied by the pressure-delivery system during inflation, DIA_{INDEX} is the diastolic pressure determined from the processed pressure waveform, and F is a mathematical constant.
9. The method of claim 1, wherein step (b) further comprises detecting the time-dependent pressure waveform representing the pressure applied to the patient's arm while the pressure-delivery system is inflating.
10. The method of claim 9, wherein step (h) further comprises digitally filtering a portion of the time-dependent pressure waveform measured during inflation to determine a processed pressure waveform.
11. The method of claim 10, wherein step (h) further comprises digitally filtering a portion of the time-dependent pressure waveform measured during inflation with: 1) a digital bandpass filter; and then 2) a digital low-pass filter to determine the processed pressure waveform.

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12. The method of claim **11**, wherein step (i) further comprises analyzing the processed pressure waveform to determine a ratio between systolic and mean arterial blood pressure.

13. The method of claim **12**, wherein step (j) further comprises processing the ratio between systolic and mean arterial blood pressure, pulse transit time, and the relationship between pulse transit time and blood pressure, to determine a systolic blood pressure value when no pressure is applied to the patient's arm with the pressure delivery system.

14. The method of claim **11**, wherein step (i) further comprises analyzing the processed pressure waveform to determine a ratio between diastolic and mean arterial blood pressure.

15. The method of claim **14**, wherein step (j) further comprises processing the ratio between diastolic and mean arterial blood pressure, pulse transit time, and the relationship between pulse transit time and blood pressure, to determine diastolic blood pressure value when no pressure is applied to the patient's arm with the pressure delivery system.

16. The method of claim **1**, wherein the pressure-delivery system comprises a cuff comprising an inflatable bladder.

17. The method of claim **16**, wherein the pressure-delivery system comprises a pneumatic system connected to the cuff and configured to inflate the cuff.

18. The method of claim **1**, wherein step (a) is performed once every 4 hours or more.

19. The method of claim **1**, wherein step (j) is performed once every 1 second or less.

20. The method of claim **19**, wherein step (j) further comprises determining an average pulse transit time from a set of pulse transit times collected over a time period.

21. The method of claim **20**, wherein the time period is between 10 and 120 seconds.

22. The method of claim **1**, wherein both the first and second sensors are selected from the group comprising an optical sensor, a pressure sensor, an electrical impedance sensor, an ECG waveform sensor, and a transducer.

* * * * *

EXHIBIT 14

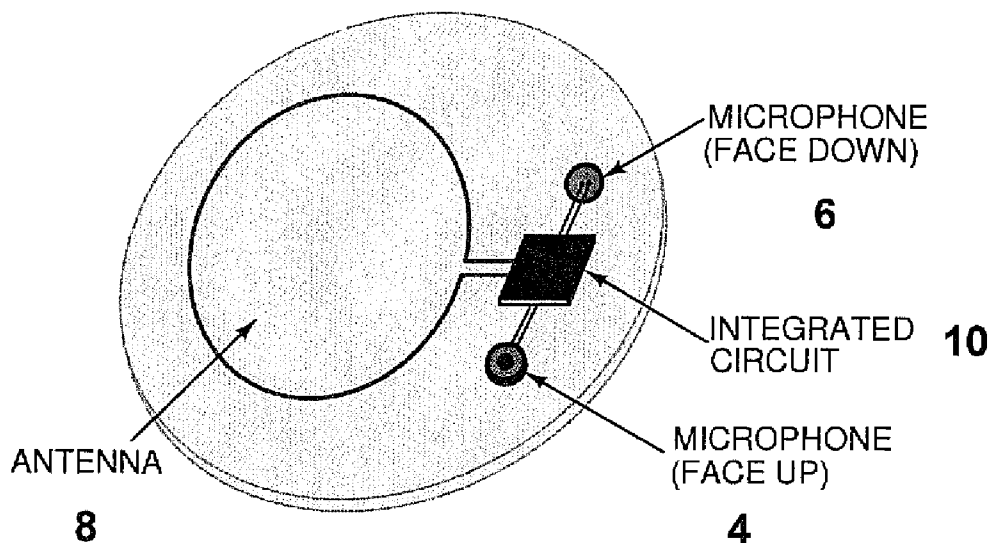
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(19) **United States**(12) **Patent Application Publication**
Turicchia et al.(10) **Pub. No.: US 2010/0198094 A1**(43) **Pub. Date: Aug. 5, 2010**(54) **WEARABLE SYSTEM FOR MONITORING
PHYSIOLOGICAL SIGNALS****Publication Classification**(76) Inventors: **Lorenzo Turicchia**, Cambridge,
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Cambridge, MA (US); **Rahul**
Sarpeshkar, Arlington, MA (US)(51) **Int. Cl.**
A61B 5/02 (2006.01)(52) **U.S. Cl. 600/528**Correspondence Address:
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BOSTON, MA 02110 (US)(57) **ABSTRACT**

A wearable system for monitoring a plurality of physiological signals is provided. The wearable system includes at least one sensor producing the physiological signals associated with a patient. A processor unit receives the physiological signals from the at least one sensor. The processor unit analyzes the physiological signals to determine the occurrence of a triggered event and produces at least one output signal identifying the triggered event. A transmission unit receives the at least one output signal and prepares for transmission of the at least one output signal.

(21) Appl. No.: **12/700,214**(22) Filed: **Feb. 4, 2010****Related U.S. Application Data**

(60) Provisional application No. 61/149,801, filed on Feb. 4, 2009.

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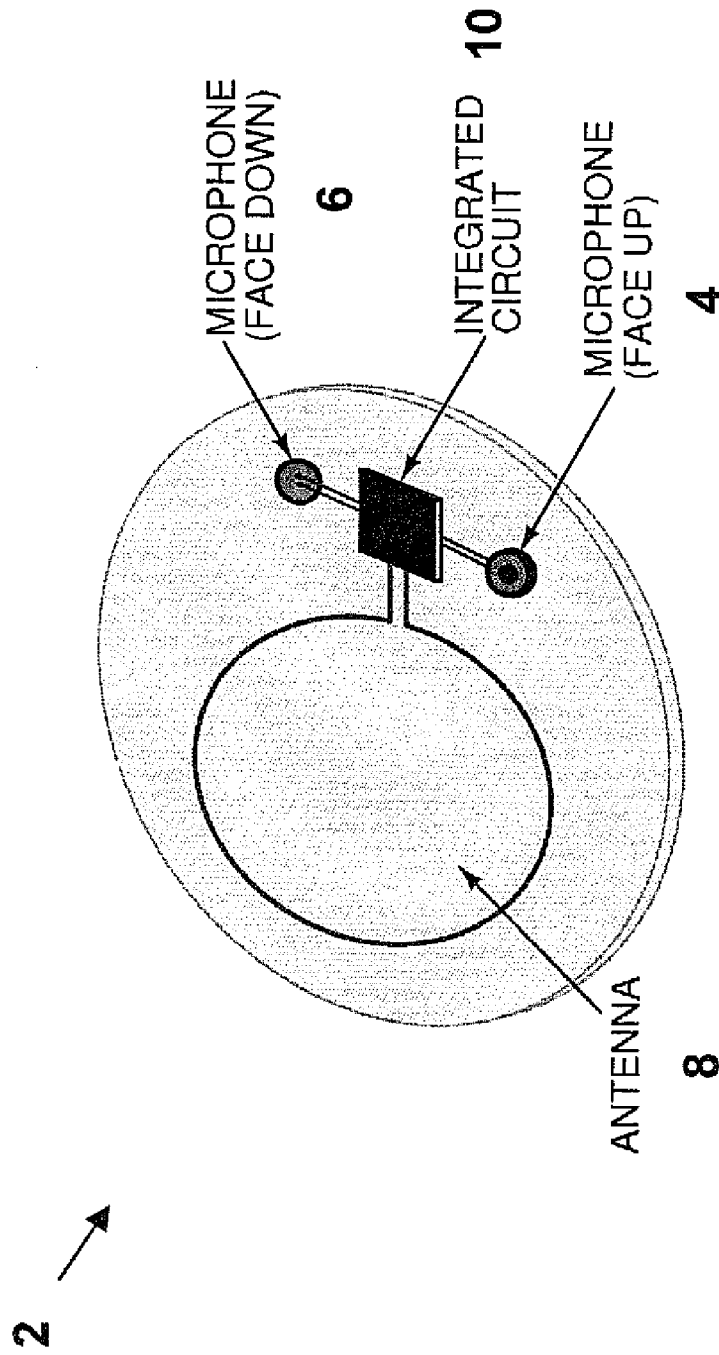


FIG. 1

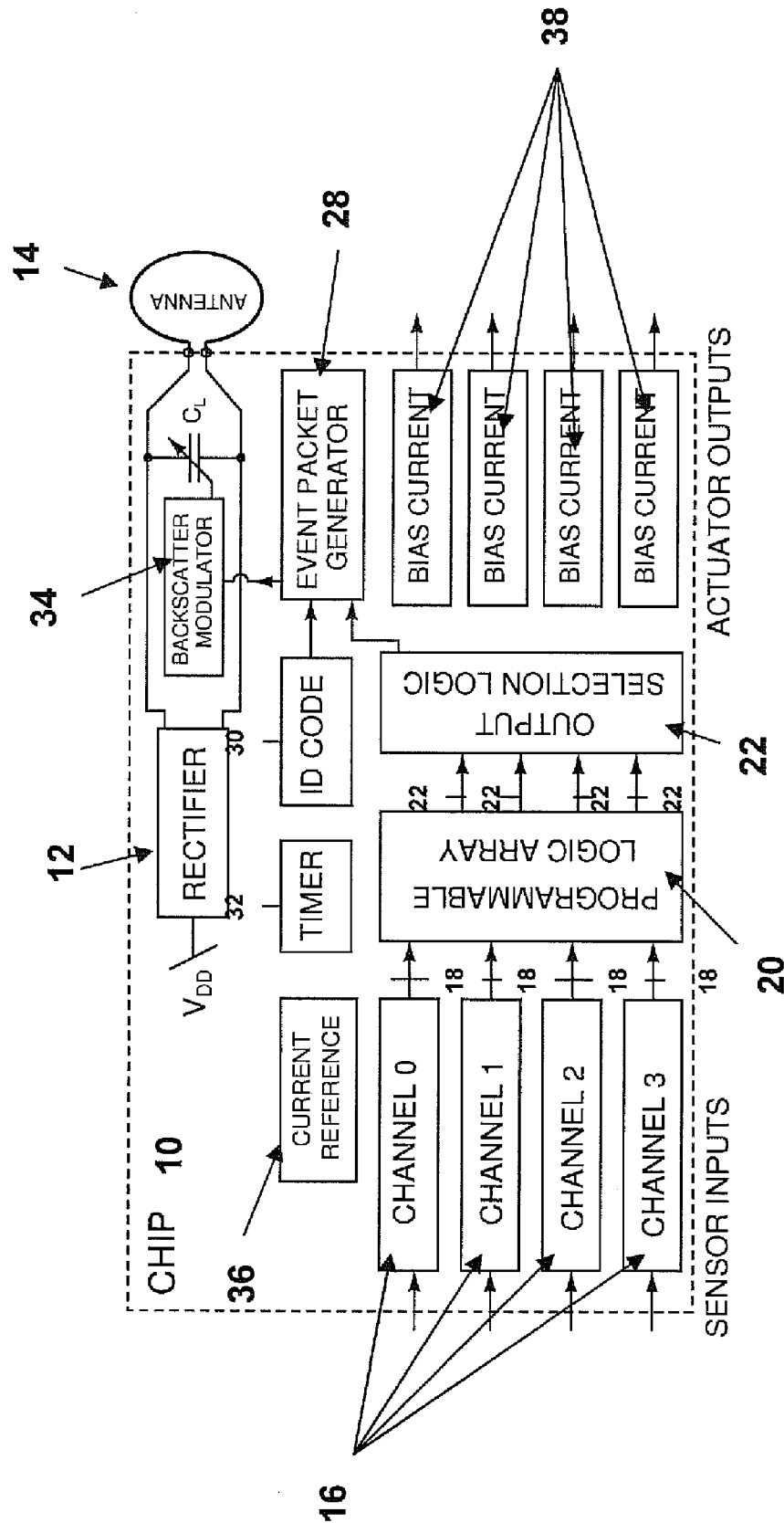


FIG. 2

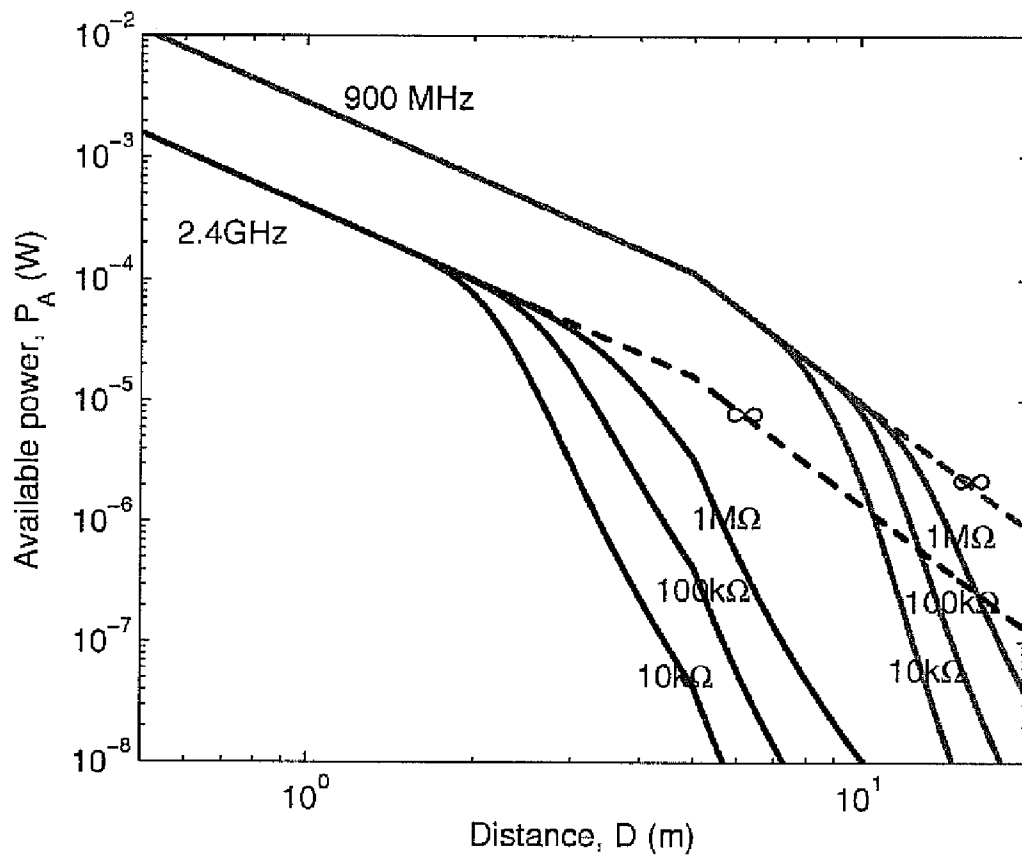


FIG. 3

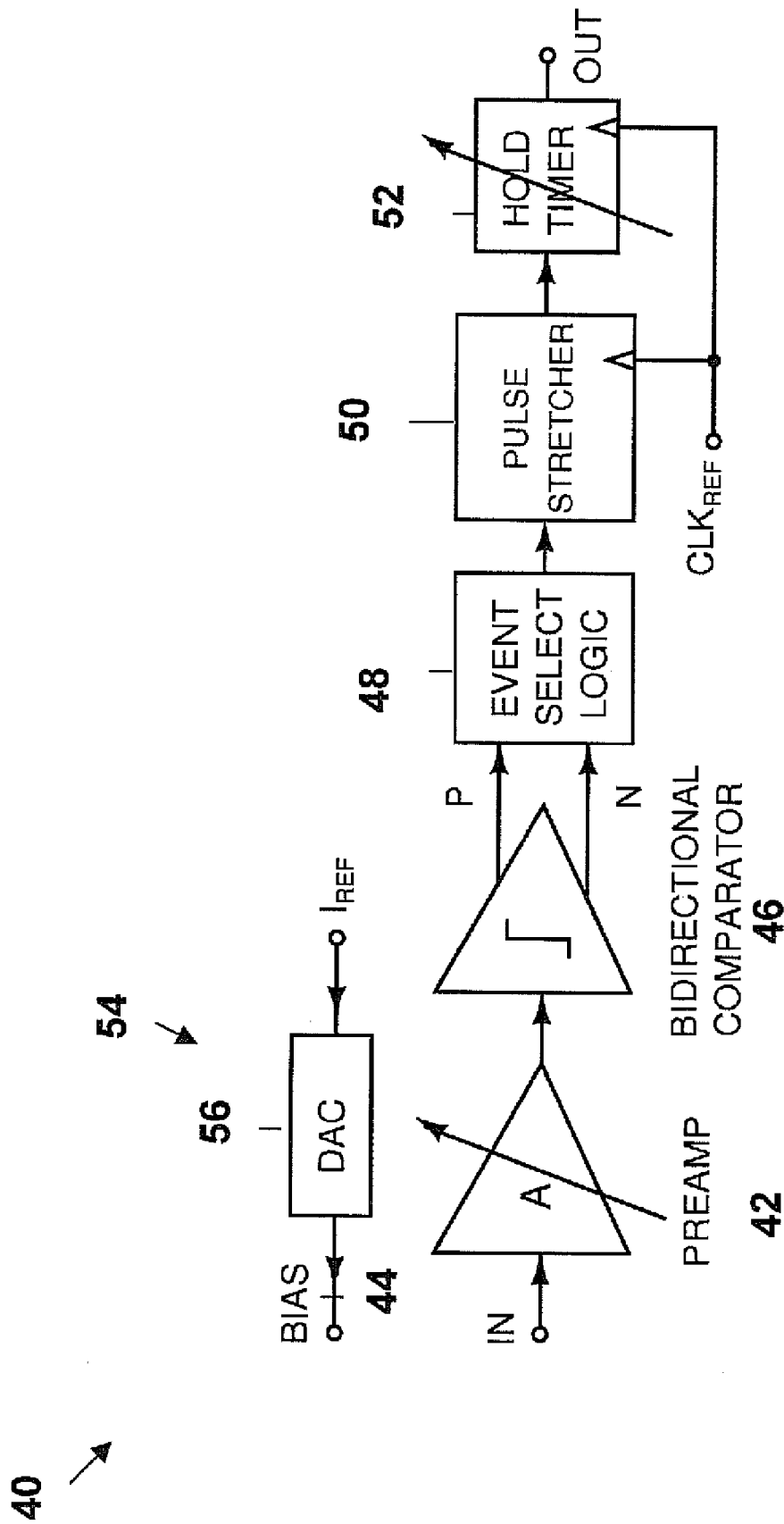


FIG. 4

FIG. 5A

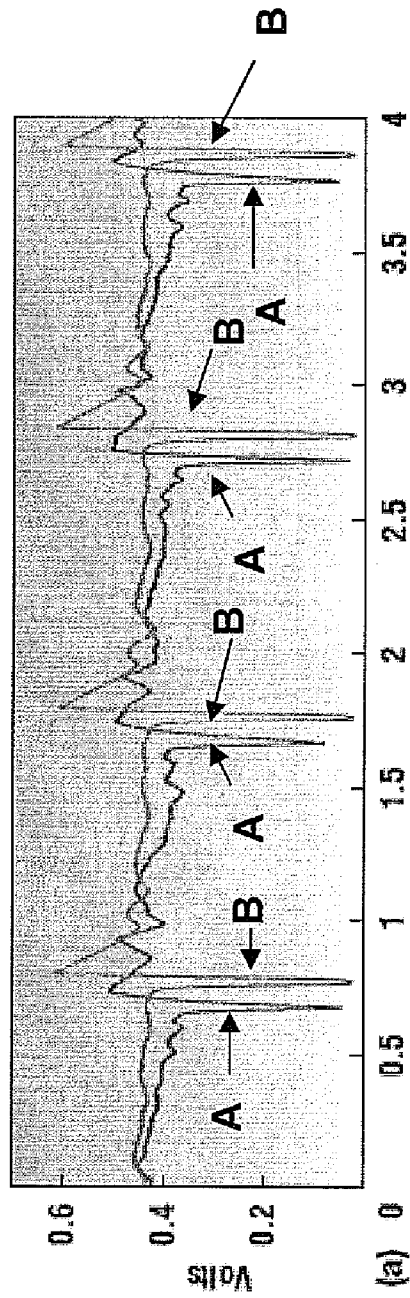
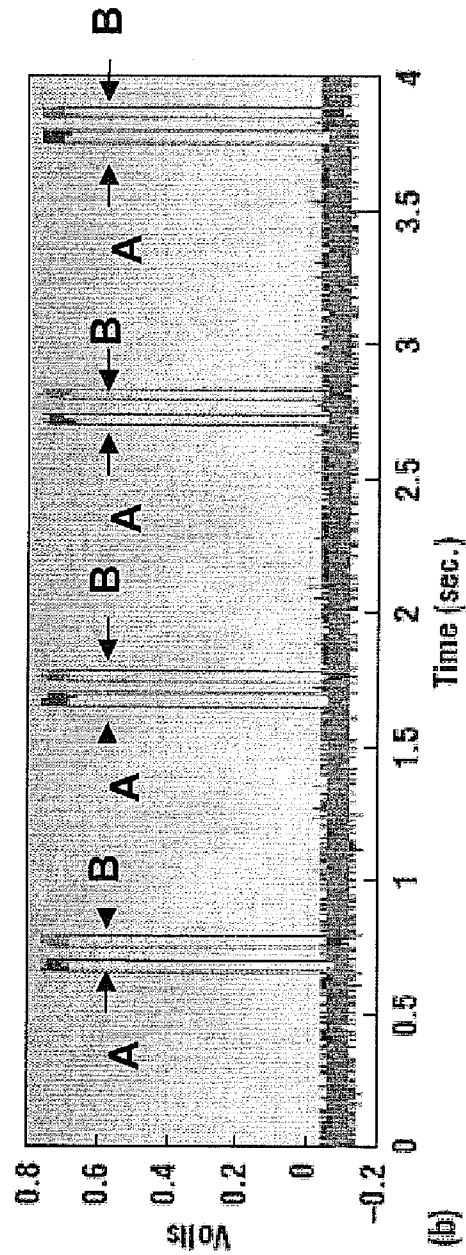


FIG. 5B



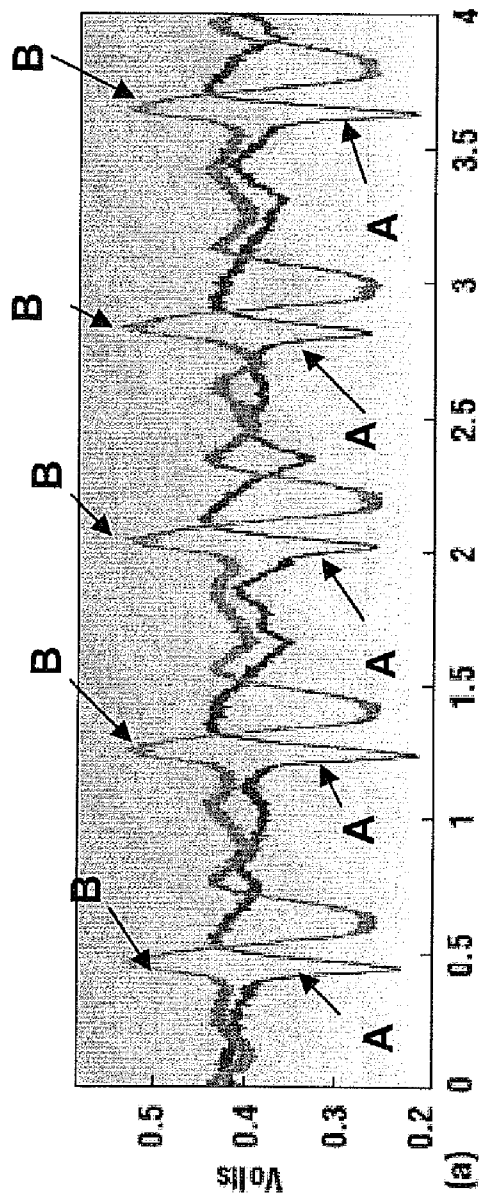


FIG. 6A

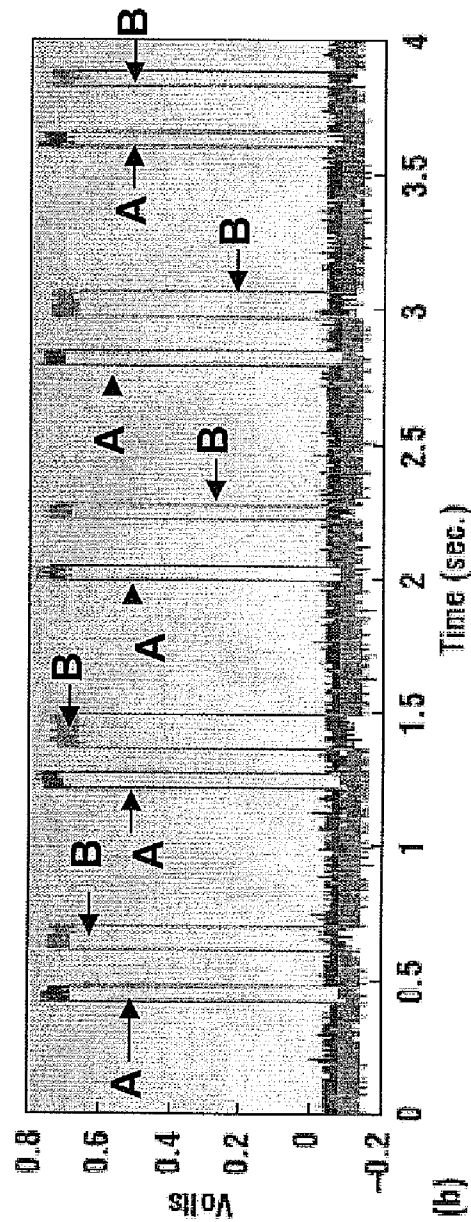


FIG. 6B

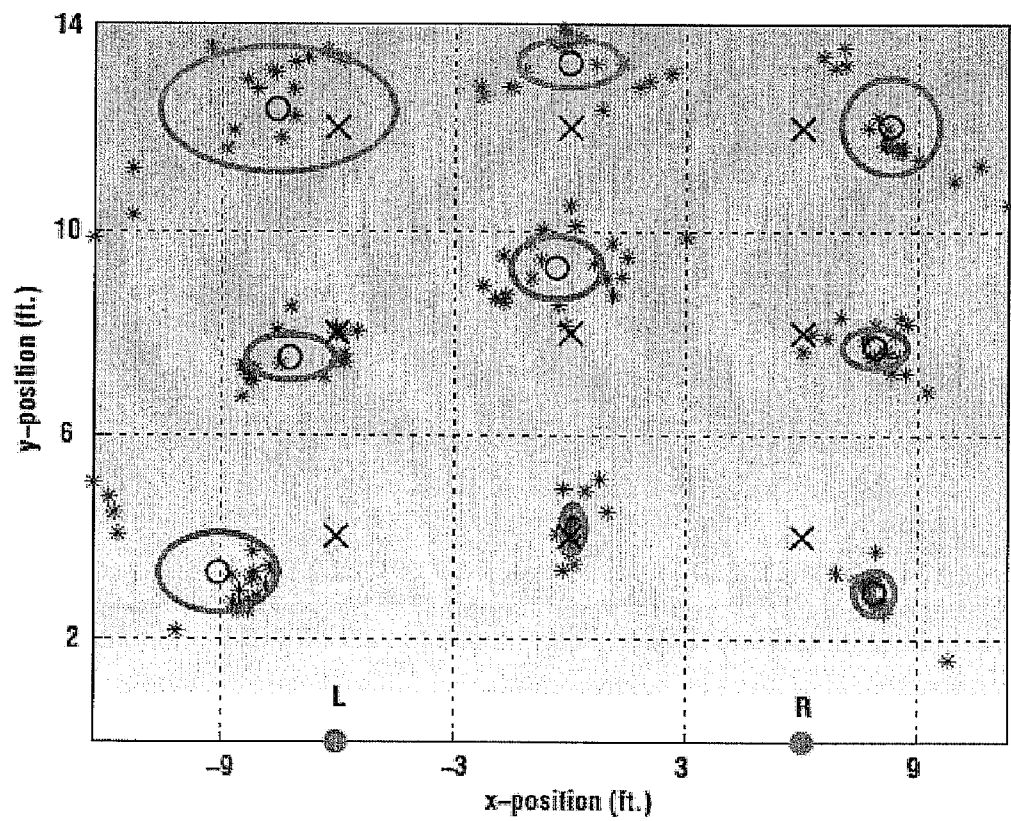


FIG. 7

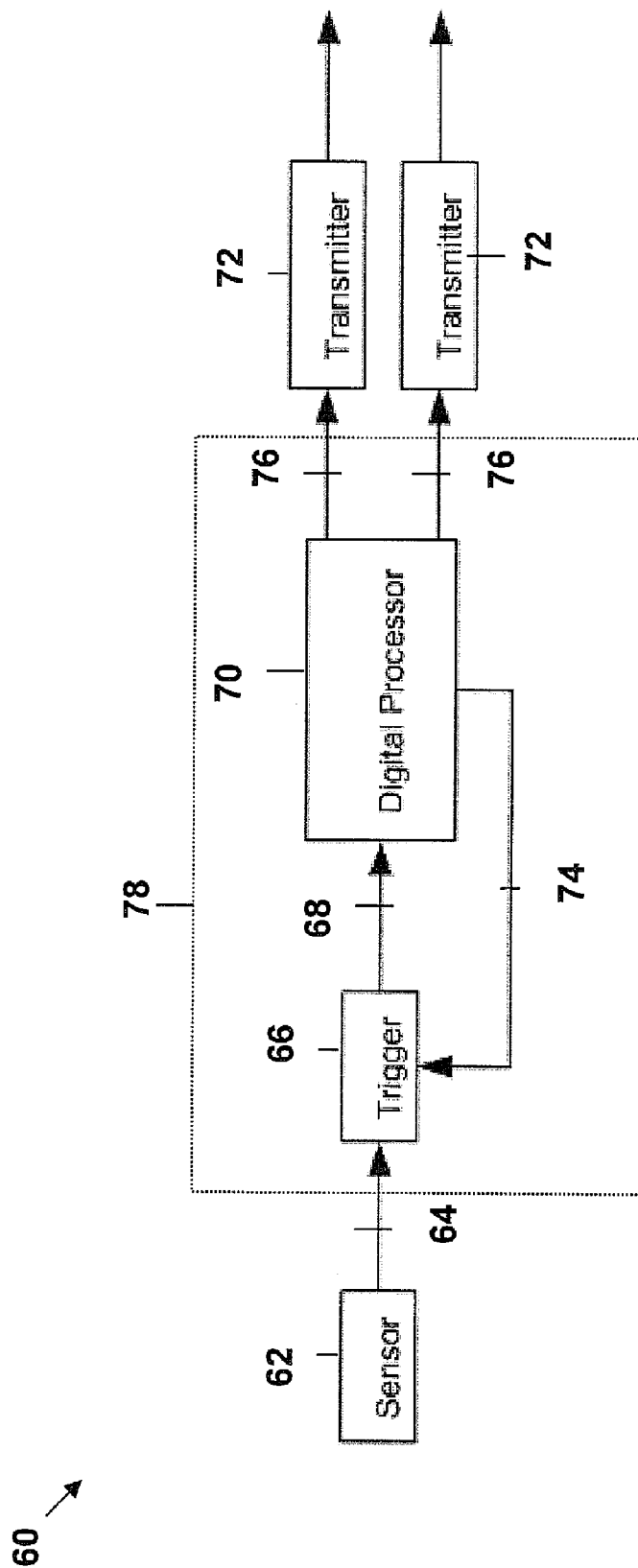


FIG. 8

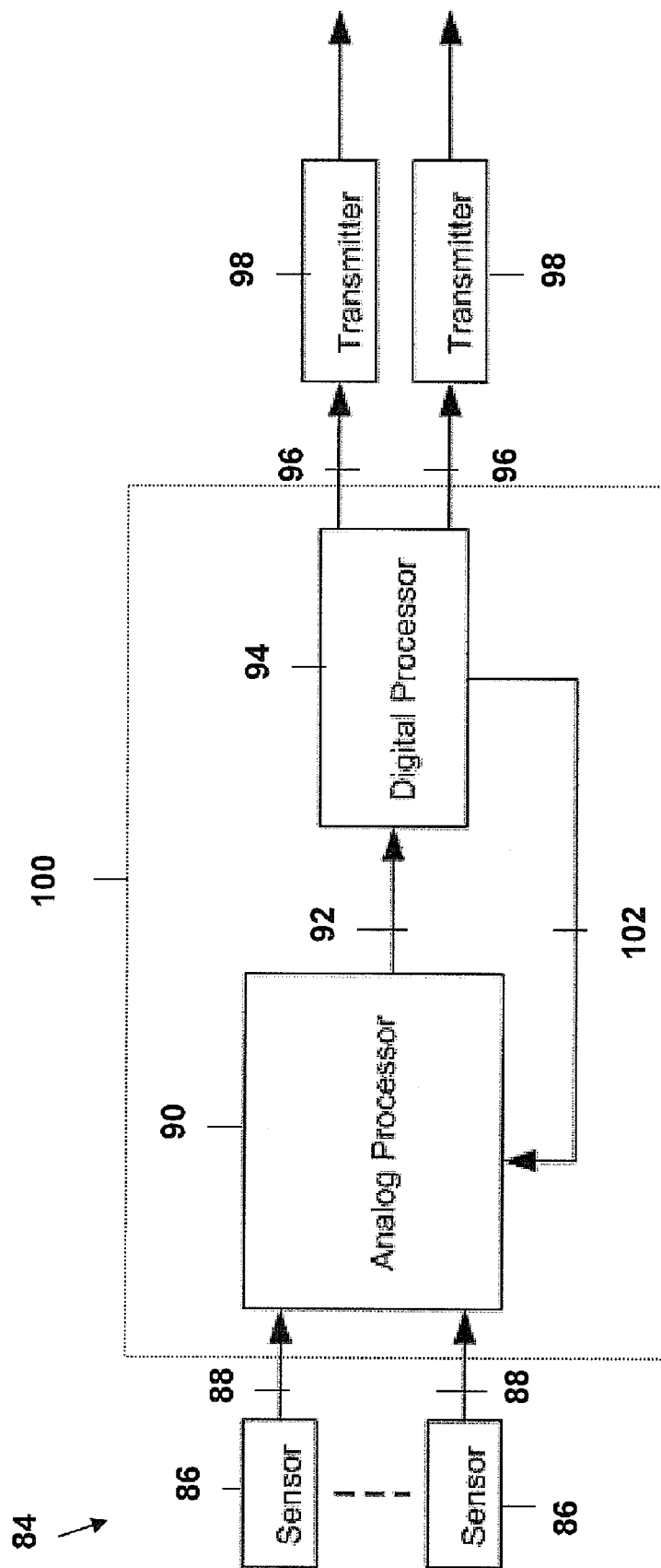


FIG. 9

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WEARABLE SYSTEM FOR MONITORING PHYSIOLOGICAL SIGNALS

PRIORITY INFORMATION

[0001] This application claims priority from provisional application Ser. No. 61/149,801 filed Feb. 4, 2009, which is incorporated herein by reference in its entirety.

BACKGROUND OF THE INVENTION

[0002] The invention is related to the field of sensors, and in particular to a wearable system for monitoring physiological signals.

[0003] With the world population aging rapidly, providing care for the elderly is becoming an increasingly important problem. For instance, more than 5,000 people experience Sudden Cardiac Arrest (SCA) every week in the United States alone. The only definitive treatment for SCA is early defibrillation: no more than 6 minutes from arrest to first shock. The chance for survival drops 10% per minute without defibrillation, and today, over 95% of SCA victims die. Since automatic defibrillators are increasingly available, pervasive monitoring of those at risk can save many lives. Infants constitute another segment of the population where pervasive monitoring could enable rapid responses to life-threatening situations. In the United States alone, approximately 2,000 infants die each year from Sudden Infant Death Syndrome (SIDS). Since slow heart-rate (bradycardia) is an important indicator of SIDS, early detection of bradycardia in infants can save many lives each year.

[0004] Wireless networks of context-aware body-mounted sensors have come into prominence recently for pervasive patient monitoring. However, to be effective, monitoring systems should be unobtrusive, robust, and low-cost.

SUMMARY OF THE INVENTION

[0005] According to one aspect of the invention, there is provided a wearable system for monitoring a plurality of physiological signals associated with a patient. The wearable system includes at least one sensor producing the physiological signals. A processor unit receives the physiological signals from the at least one sensor. The processor unit analyzes the physiological signals to determine the occurrence of a triggered event and produces at least one output signal identifying the triggered event. The processor unit is operable for harvesting RF energy to power the wearable system or only said at least one sensor. A transmission unit receives the at least one output signal and prepares for transmission of the at least one output signal.

[0006] According to one aspect of the invention, there is provided a wearable system for monitoring a patient. The wearable system includes a first microphone for detecting environmental sounds and outputting a first signal. A second microphone detects the patient's physiological status or environmental sounds and produces a second signal. A processor unit receives the first signal and second signal. The processor unit analyzes the first signal and the second signal to determine the occurrence of a triggered event and produces at least one output signal identifying the triggered event. A transmission unit receives the at least one output signal and prepares for transmission of the at least one output signal.

[0007] According to another aspect of the invention, there is provided a method for remotely monitoring a plurality of physiological signals using a wearable system. The method

includes providing at least one sensor producing the physiological signals associated with a patient. Also, the method includes receiving the physiological signals from the at least one sensor using a processor unit. The processor unit analyzes the physiological signals to determine the occurrence of a triggered event and produces at least one output signal identifying the triggered event. Also, the processor unit harvests RF energy for powering the wearable system or only said at least one sensor. Moreover, the method includes sending the at least one output signal to a transmission unit for transmission.

BRIEF DESCRIPTION OF THE DRAWINGS

[0008] FIG. 1 is a schematic diagram illustrating an embodiment of the invention having two microphones and an antenna attached to a flexible, adhesive surface;

[0009] FIG. 2 is a schematic block diagram illustrating a low-power patient-monitoring integrated circuit or chip;

[0010] FIG. 3 is a graph illustrating harvested RF power available as a function of distance from the transmitter for different load resistances at 900 MHz and 2.4 GHz;

[0011] FIG. 4 is a schematic block diagram illustrating a single signal-processing channel used in accordance;

[0012] FIGS. 5A-5B are PCG and PPG waveforms measured at the wrist and fingertip;

[0013] FIGS. 6A-6B are PCG and PPG waveforms measured at the wrist and fingertip using an oximeter;

[0014] FIG. 7 is a schematic diagram illustrating measured microphone positions produced in accordance with the invention;

[0015] FIG. 8 is a schematic block diagram illustrating another embodiment of the invention; and

[0016] FIG. 9 is a schematic diagram illustrating another embodiment of the invention using one or more sensors and an analog processor.

DETAILED DESCRIPTION OF THE INVENTION

[0017] The invention provides a low-power, battery-free tag for use in pervasive sensing applications such as wearable patient-monitoring systems or body sensor networks. The tag includes of a custom integrated circuit, an antenna for RF energy harvesting, and several sensors for monitoring important physiological parameters and generating alarms when necessary. By using several physiological signals and/or multiple sensors, one can reduce the risk of false alarms being generated. The chip can include four independently-programmable channels that generate asynchronous spikes when biomedical signals cross a programmable threshold voltage. Spike duration and maximum spiking rate are also programmable. Spikes on different channels can be combined using a programmable logic array (PLA). Each channel can also actuate an external sensor by supplying DC current. When not powering external sensors, the chip consumes only 1.0 μ W of power. Experimental results with phono-cardiogram (PCG) and photo-plethysmogram (PPG) signals show the effectiveness of the invention. It has been also demonstrated that one can localize the tag to within 0.6 m by using an audio localization scheme.

[0018] The invention uses multiple sensors to generate three types of alarm: disconnection from the body, device malfunction, and patient emergency. For example, FIG. 1 shows an example of a patient-monitoring tag system 2 having two microphones 4, 6, one facing up 4 (away from the

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body) and the other facing down **6**. The downward-facing microphone **6** monitors heart sounds, while the upward-facing microphone **4** is usually switched off to save power. It is turned on only when the downward-facing microphone **6** does not detect any heart sounds and a disconnection or patient emergency is suspected. If both microphones **4**, **6** now pick up similar environmental sounds, a 'disconnection alarm' is generated since it is probable that the tag is no longer in proximity to the skin. A 'patient emergency alarm' is generated if the downward-facing microphone **6** does not pick up environmental sounds, but the upward-facing microphone **4** does, since in this case it is likely that the tag **2** is still attached and the heart has stopped. If neither microphone **4**, **6** picks up any sounds, the tag is probably malfunctioning; therefore a 'device malfunction alarm' is generated.

[0019] Each tag contains a unique identification code and powers up using harvested RF power. A fixed base station communicates with multiple tags and decides, based on transmitted patient data, if an alarm should be triggered. Such a system will be useful for hospitals, facilities that care for infants and the elderly, and also ordinary homes. In order to quickly cover a large fraction of the population at risk one needs to keep the tag low-cost (ideally, less than \$2 each when manufactured in volume), disposable, small and easy to use. A low-power custom integrated circuit or chip **10** is used that forms the central component of the patient-monitoring tag **2** and demonstrate its power harvesting, sensing and actuation capabilities.

[0020] A block diagram of the integrated circuit or chip **10** is shown in FIG. **2**. It was designed to be extremely low power by incorporating only minimally acceptable amounts of computation and signal processing, most complexity is transferred to the fixed base station. The chip **10** can harvest radiated RF power, making a low-cost battery-free tag possible. An efficient two-stage CMOS rectifier **12** is connected to an external loop antenna **14**. The input capacitance of the chip **10**, C_L resonates with the inductive input reactance of the antenna at the operating frequency. The resultant L-type impedance match provides passive voltage gain that reduces the amount of RF power needed to overcome the dead-zone of the rectifier **12**, thereby increasing operating range. The first rectifier stage is designed to have low output impedance since it powers up external sensors, which typically consume much more power than the chip itself. The second stage, which provides a higher-impedance output, is used to power up (V_{DD}) the chip **10**. Over-voltage protection circuits at the power supply and RF input nodes prevent damage due to large RF amplitudes.

[0021] One can now calculate P_d , the RF power that can be harvested at different distances D from the transmitter. Path loss models predict the fall-off of radiated power density P_r (in W/m²) with D . A simple version commonly used for modeling indoor environments recognizes two zones: P_r proportional to D^{-n_1} for $D < D_0$, and P_r proportional to D^{-n_2} for $D > D_0$, where D_0 , n_1 and n_2 are constants. Typically n_1 is approximately equal to 2, the free-space value, and n_2 varies between 2.5 and 4. The value of n_2 exceeds 2 because of absorption and reflection of the RF by environmental obstacles, such as furniture and people. The following conservative values: $D_0=5$ m, $n_1=2$, $n_2=3.5$ are used.

[0022] Combining the predicted path loss with the rectifier model gives us FIG. **3**. FIG. **3** assumes that the equivalent isotropic radiated power (EIRP) is 4 W, which is the maximum allowed in the United States for radio-frequency iden-

tification (RFID) applications. It shows P_d as a function of D at two popular RFID frequencies: 900 MHz and 2.4 GHz. The main reason for going to higher operating frequencies is to reduce the physical size of the antenna. Loop antennas are normally operated at their first resonant frequency. At this frequency the circumference of the loop is half the wavelength. Therefore a single-turn circular loop has a diameter of 5.3 cm at 900 MHz and 2.0 cm at 2.4 GHz. Multiple-turn loops can be used to reduce antenna size at the cost of increased fabrication complexity.

[0023] The various curves in FIG. **3** correspond to different load resistances R_L driven by the rectifier. They decrease rapidly at large distances because the received RF amplitude becomes smaller than the rectifier's dead zone. The load resistance is usually dominated by the power consumed by off-chip sensors and not the chip itself. For example, a microphone biased at 30 μ A and 0.5V (typical values used in our experiments) dissipates 15 μ W, corresponding to an effective load driven by the rectifier of $R_L=16.7$ kOhm.

[0024] FIG. **3** then predicts an operating range of approximately 12 m at 900 MHz and 3 m at 2.4 GHz. In practice the reliable operating range will be somewhat smaller because some tags will be mistuned by their proximity to conductive and dielectric surfaces. In addition, one has to allow for transient drops in received RF power level (fades), which are ubiquitous in indoor environments because the received signal is the superposition of multiple waves with time-varying amplitude and phase. Nevertheless, a single base-station operating at 900 MHz is sufficient for a moderately-sized room.

[0025] The chip **10** includes four independent channels **16** that can be used to interface with various types of sensors. The outputs **18** of these channels **16** are digital spikes, i.e., 'event' signals. These signals can be combined in a flexible way using a programmable logic array (PLA) **20** that can implement a variety of Boolean logic functions. In this case, the PLA **20** is a four-input four-output design with an 8x8 AND plane and a 4x8 OR plane. The PLA **20** allows implementing any of the 216 possible logic functions of four inputs **18** for any of its four outputs **22** in a programmable fashion. These outputs **22** can be monitored individually, allowing us to implement rudimentary sensor-fusion algorithms that combine the outputs of multiple channels. Programmable output selection logic **24** multiplexes the four PLA outputs **22** into a single signal that is transmitted to the base station as "event packets" using the event packet generator **28** that includes a chip identification code **30** and time stamps provided by a timer **32**. Data is transmitted using a backscatter modulator **34** that includes a 100 fF capacitor being added and subtracted from C_L to change the amount of RF power scattered by the tag. Backscatter modulation is popular in passive RFID systems because all the complexity and power consumption is pushed to the base station, the tag remains simple and low-power. A current reference source **36** provides current to one or more bias current circuits **38** producing bias current to power up other sensors.

[0026] A block diagram of a single channel **40** is shown in FIG. **4**. The preamplifier **42** includes a common source stage with capacitive feedback. The size of the feedback capacitor can be varied between C_0 and $16C_0$ to set the gain. The amplifier **42** incorporates DC rejection, i.e., the transfer function is band-pass with a very low cut-in frequency (typically <1 Hz). It uses a nominal bias current **44** of 10 nA and $C_0=0.5$ pF resulting in a bandwidth that decreases from 12 KHz to 6

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KHz as the gain increases from 1 to 16. A matched copy of the amplifier (minus the capacitors) is used to determine the quiescent operating point.

[0027] The comparator **46** generates events whenever the output voltage of the amplifier **42** differs from its quiescent value by more than a fixed threshold voltage $V_{th}=80$ mV. There are two types of events: positive-going, when the output voltage is larger than its quiescent value by V_{th} or more, and negative-going, when it is smaller. The smallest input amplitude that triggers a spike decreases from V_{th} to $V_{th}/16$ (80 mV to 5 mV) as the preamplifier **42** gain increases from 1 to 16.

[0028] Event selection logic **48** is connected to the comparator output in each channel P,N and allows only positive or negative-going spikes, both, or neither to be detected. This combinational block **48** is followed by a pulse-stretcher circuit **50** that adds hysteresis in the time domain to prevent multiple comparator transitions due to noise when an event is detected. It also ensures that output spikes always last long enough for at least one complete data packet to be broadcasted during every spike. The pulse-stretcher circuit **50** is a digitally-timed one-shot. It allows an incoming event edge to set its output high, and a delayed version of this edge to reset it low.

[0029] The pulse-stretcher circuit **50** is followed by a programmable hold timer circuit **52**. This circuit **52** imposes a hold time T_{hold} after each spike, during which no new spikes can be generated. By placing an upper bound of $1/T_{hold}$ on the spiking rate, the hold timer circuit **52** greatly reduces the probability of timing collisions between different tags. The average value of T_{hold} can be varied between 94 ms and 1.4 s.

[0030] A programmable DC current source **54** was designed for every channel. This current source **54** can be used to power up external sensors, such as microphones, and includes a 8-bit binary-weighted current DAC that can supply between $0.5 \mu A$ and $128 \mu A$ of BIAS current **44** depending on the input current I_{ref} . To reduce power consumption, the chip was designed to operate on power supply voltages as low as 0.8V (core) and 0.5V (programmable current sources).

[0031] An on-chip serial interface allows the user to program the PLA **20**, channel selection logic **12**, 16-bit chip identification code **30**, and channel parameters such as sensor current, preamplifier gain and hold time. The static power consumption with no external sensors is only $10 \mu W$. The power consumption with sensors presented depends on their bias currents, which are application-dependent.

[0032] The invention can use a microphone to detect heart sounds. Commercial microphones contain built-in JFET preamplifiers. The microphone is biased at much lower currents than recommended by the manufacturer to save power. In this regime the JFET is unsaturated and acts as a voltage-controlled resistor, making signal gain proportional to the bias current. By varying with the on-chip DAC one can trade-off sensitivity with bandwidth and power consumption. In practice one can save considerable amounts of power because heart sounds are relatively loud and low in bandwidth (typically, 20-250 Hz). A Panasonic omnidirectional electret condenser microphone (WM-63PR) in a plastic enclosure is used. The WM-63PR was selected since it is a small, thin device (diameter=6 mm, thickness=1.3 mm) that is also cheap. Similar microphones that are even cheaper can also be used since sound quality is not critically important.

[0033] Microphones are normally placed on the chest for monitoring heart activity. However, the microphone membrane cannot vibrate freely if it is directly attached to the skin. Therefore one can add a small air chamber (approximately 1 mm thick) below the sensor. The chamber has no vents, reducing the amount of ambient noise, but its diameter and shape have little effect on sound pickup.

[0034] Microphones are biased using on-chip current sources operating on a 0.5V supply. In the first case, two microphones are connected to channels on the chip and attached to the neck and wrist of a subject. These positions were selected since a strong pulse was expected at these locations. Each microphone is biased at $30 \mu A$ and the preamplifier gain was set to 8. In other cases, the sensor was placed at its default position, the chest. In this position heart sounds are louder, enabling the microphone bias current to be further reduced. Note other types of sensors beside microphones can be used, such as piezo-electric transducers.

[0035] FIGS. 5A-5B are PCG (A) and PPG (B) waveforms measured at the wrist and fingertip, respectively. In particular FIG. 5A shows the preamplifier analog output within each channel and FIG. 5B shows the final digital event, or spike, that each channel generates. The waveform A at the wrist is delayed relative to the waveform B at the neck by about 95 ms because of the time taken by the systolic pulse to propagate down the length of the arm. This delay can be used to provide information about blood pressure. Each large negative spike is caused by the systolic upsurge in blood pressure and consequent dilation of the arteries. There are two reasons why the high-frequency components found in a conventional PCG (A) waveform are almost completely absent in these recordings. Firstly, the coupling between the skin and the microphone is a low-pass filter. Secondly, microphone sensitivities were deliberately kept low by reducing their bias currents. This was because heart rate information was of interest, which resides in the loud, low-frequency components of the PCG (A) (from 10-80 Hz).

[0036] Also, one can combine the wrist microphone (still biased at $30 \mu A$) with an external pulse oximeter connected to another channel. The oximeter, which is used to measure oxygen saturation level in the blood, is attached to the index finger of the subject. Pulse oximeters can also be used to measure variations in the optical density of transmission in the arteries due to their contraction and relaxation as a function of time. Such a recording is known as a photo-plethysmogram, or PPG. For simplicity, one can use an off-the-shelf infra-red LED light source and a Texas Instruments OPT101 photo-sensor. The OPT101 includes a photodiode and transimpedance amplifier integrated into a single package. Its output is fed into the chip **10**. FIGS. 6A-6B are PCG (A) and PPG (B) waveforms measured at the wrist and fingertip, respectively. In particular FIG. 6A shows the preamplifier analog output within each channel and FIG. 6B shows the final digital event, or spike, that each channel generates. The peaks in the PPG (B) waveform line up with the negative spikes in the PCG (A) because it is recorded from adjacent locations, i.e., the pulse propagation delay from the wrist to the finger is small.

[0037] As a final example of the chip's capabilities, one can demonstrate that it can be localized within a room using acoustic time-of-flight measurements. Such a system will only be turned on during a suspected patient emergency to aid in localizing the patient and also possibly providing an audio alarm. One can use a single microphone attached to the chip

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and two speakers (L and R) placed a distance d apart. By measuring the time delays t_1 and t_2 between when each speaker beeps and the chip starts generating spikes, one can locate the position of the microphone in two dimensions.

[0038] The microphone was biased at 128 μ A and preamplifiers from two channels are cascaded to give a total gain of $8 \times 12 = 96$. Small, cheap speakers are placed $d = 12$ ft apart and programmed to transmit 100 ms tone bursts at 230 Hz. The burst frequency was kept as low as possible to minimize audibility and attenuation with distance, but was limited by the poor low-frequency response of the small speakers being used. The bursts were spaced 400 ms apart to ensure that all echoes from the first burst would die down before the second one arrived. The measured sound level at the center of the room with either speaker on was 87 dB SPL, which is loud enough to serve as an alarm signal.

[0039] The propagation times t_1 and t_2 from the speaker to the microphone are estimated by measuring the time between the onset of each burst and the first spike detected by the chip. These times were estimated using a simple threshold-based algorithm. The distances of the microphone from each speaker are given by $d_1 = ct_1$ and $d_2 = ct_2$, where $c = 1130$ ft/s is the speed of sound in air.

[0040] The measured microphone positions are shown in FIG. 7 for 9 different positions and 20 trials. The average standard deviation in the measured positions was 1.4 ft (0.43 m), and the average error between the measured and actual positions was 1.97 ft (0.6 m). Positions closer to the speakers were more accurately measured than distant ones because of the realistic indoor environment, which included sound propagation barriers in the shape of furniture and people. The current accuracy of the system already provides important information about the location of the patient. For example, one can distinguish between the bed, a chair and the bathroom. Accuracy can be further increased if necessary by using a higher transmission frequency to improve timing precision. However, since propagation losses increase with frequency, louder sounds are needed. An attractive alternative in this context is to use ultra-sound. Finally, the localization strategy can be easily extended to three dimensions by adding a third speaker.

[0041] The audio alarm and localization technique that has been described can be extended to other wireless sensor applications. For example, it can form the basis for sensor-fusion algorithms where sensors such as video cameras that provide high-bandwidth information can be activated by the audio alarm only when abnormal events are detected. The amount of information that needs to be continuously monitored by a human operator is thereby reduced.

[0042] FIG. 8 is a schematic block diagram illustrating another embodiment of the invention. In particular, FIG. 8 shows a wearable patient-monitoring tag system 60 having a sensor 62 providing a signal 64 to be received by a trigger module 66. The trigger module 66 analyzes the signal 64 to determine if it includes values that can trigger an event to a base station and then outputs a signal 68. A digital processor 70 receives the signal 68 and performs the necessary digital operations to allow the contents of the signal 68 to be transmitted by outputting one or more signals 76 to one or more transmitters 72. Note the digital processor can adjust the properties of the trigger module using a signal 74. Also, the trigger module 66 and digital processor 70 and their respective output signals 68, 76 form a processor structure 78 that can either be an integrated circuit or chip.

[0043] FIG. 9 is a schematic diagram illustrating another embodiment of the invention using one or more sensors and an analog processor. In particular, FIG. 8 shows a wearable patient-monitoring tag system 84 having one or more sensors 86 providing one or more signals 64 to be received by an analog processor 90. The analog processor 90 analyzes the signal 88 to determine if it includes values that can trigger an event to a base station and then outputs a signal 92. A digital processor 94 receives the signal 92 and performs the necessary digital operations to allow the contents of the signal 92 to be transmitted by outputting one or more signals 96 to one or more transmitters 98. The digital processor 94 can adjust the properties of the analog processor 90 using a signal 102. Note that the trigger module is not shown explicitly but it can to be included within either the analog signal processor 90 or the digital signal processor 94 in certain embodiments. Also, the analog processor 90 and digital processor 94 and their respective output signals 94, 96 form a processor structure 100 that can either be an integrated circuit or chip.

[0044] Although the present invention has been shown and described with respect to several preferred embodiments thereof, various changes, omissions and additions to the form and detail thereof, may be made therein, without departing from the spirit and scope of the invention.

What is claimed is:

1. A wearable system for monitoring a plurality of physiological signals associated with a patient, comprising:
 - at least one sensor for producing said physiological signals;
 - a processor unit for receiving said physiological signals from said at least one sensor, said processor unit analyzing the physiological signals to determine the occurrence of a triggered event and producing at least one output signal identifying the triggered event, the processor unit operable for harvesting RF energy to provide power to the wearable system or only said at least one sensor; and
 - a transmission unit for receiving the at least one output signal and preparing for transmission of the at least one output signal.
2. The wearable system of claim 1, wherein the at least one sensor comprises a plurality of microphones.
3. The wearable system of claim 1, wherein the at least one sensor comprises a plurality of transducers.
4. The wearable system of claim 2, wherein one of the microphones monitors environmental sounds.
5. The wearable system of claim 1, wherein the physiological signals comprise a heartbeat.
6. The wearable system of claim 4, wherein the environmental sounds indicate whether the patient is wearing the wearable system.
7. The wearable system of claim 1, wherein the processor unit comprises an arrangement having a trigger module and digital processor.
8. A wearable system for monitoring a patient comprising:
 - a first microphone for detecting environmental sounds and outputting a first signal;
 - a second microphone for detecting the patient's physiological status or environmental sounds and producing a second signal;
 - a processor unit for receiving said first and second signal, said processor unit analyzing the first signal and the

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second signal to determine the occurrence of a triggered event, and producing at least one output signal identifying the triggered event; and

a transmission unit for receiving the at least one output signal and preparing for transmission of the at least one output signal.

9. The wearable system of claim 8, wherein said physiological signs comprise heartbeats.

10. The wearable system of claim 8, wherein said processor unit produces a patient disconnect signal when said first microphone and the second microphone detect environmental sounds.

11. The wearable system of claim 8, wherein said processor unit produces a patient alarm signal when the first microphone detects environmental sounds and the second microphone detects no physiological sign.

12. The wearable system of claim 8, wherein said processor unit produces a malfunction signal when the first microphone and the second microphone detect no environmental sounds.

13. The wearable system of claim 8, wherein the transmission unit comprises an antenna.

14. A method for remotely monitoring a plurality of physiological signals using a wearable system comprising:

providing at least one sensor producing said physiological signals associated with a patient;

receiving said physiological signals from said at least one sensor using a processor unit, said processor unit analyzing the physiological signals to determine the occurrence of a triggered event and producing at least one output signal identifying the triggered even, the processor unit harvests RF energy for powering the wearable system or only said at least one sensor; and

sending the at least one output signal to a transmission unit for transmission.

15. The method of claim 14, wherein the at least one sensor comprises a plurality of microphones.

16. The method of claim 14, wherein the at least one sensor comprises a plurality of transducers.

17. The method of claim 15, wherein one of the microphones monitors environmental sounds.

18. The method of claim 14, wherein the physiological signal comprise a heartbeat.

19. The method of claim 17, wherein the environmental sounds indicate whether the patient is wearing the wearable system.

20. The method of claim 14, wherein the processor unit comprises an arrangement having a trigger module and digital processor.

* * * * *

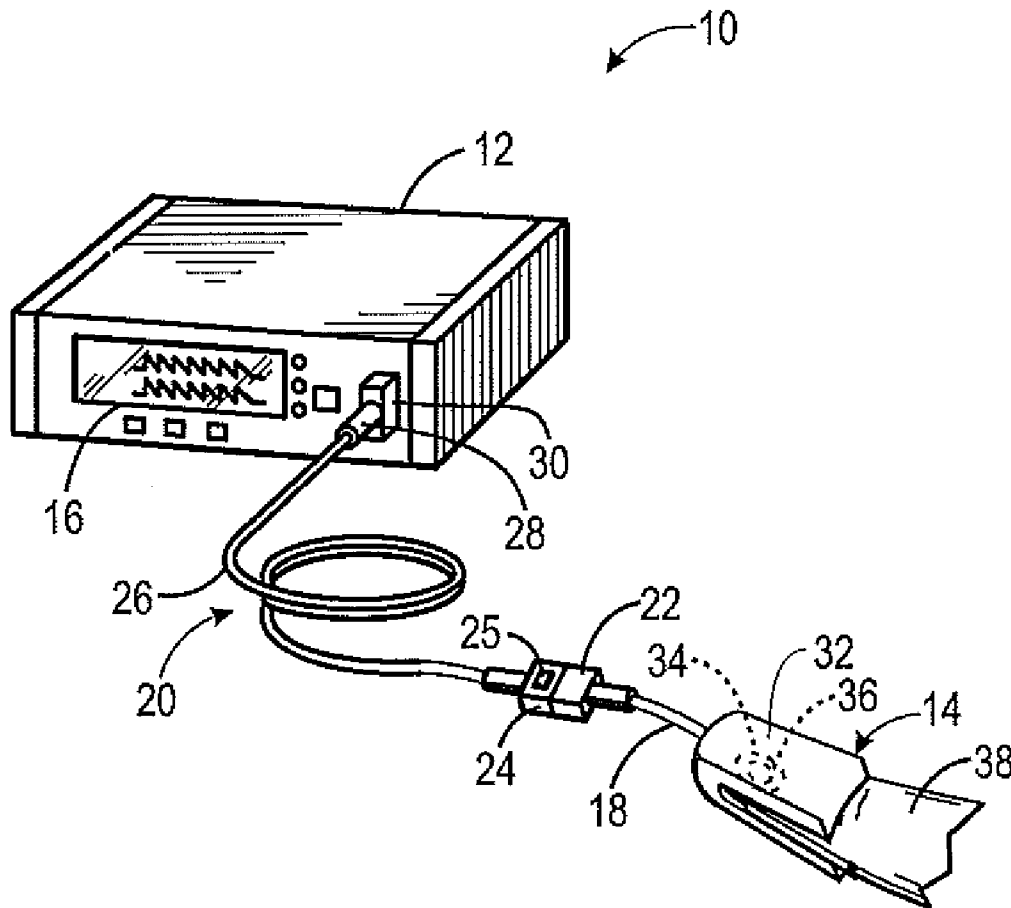
EXHIBIT 15

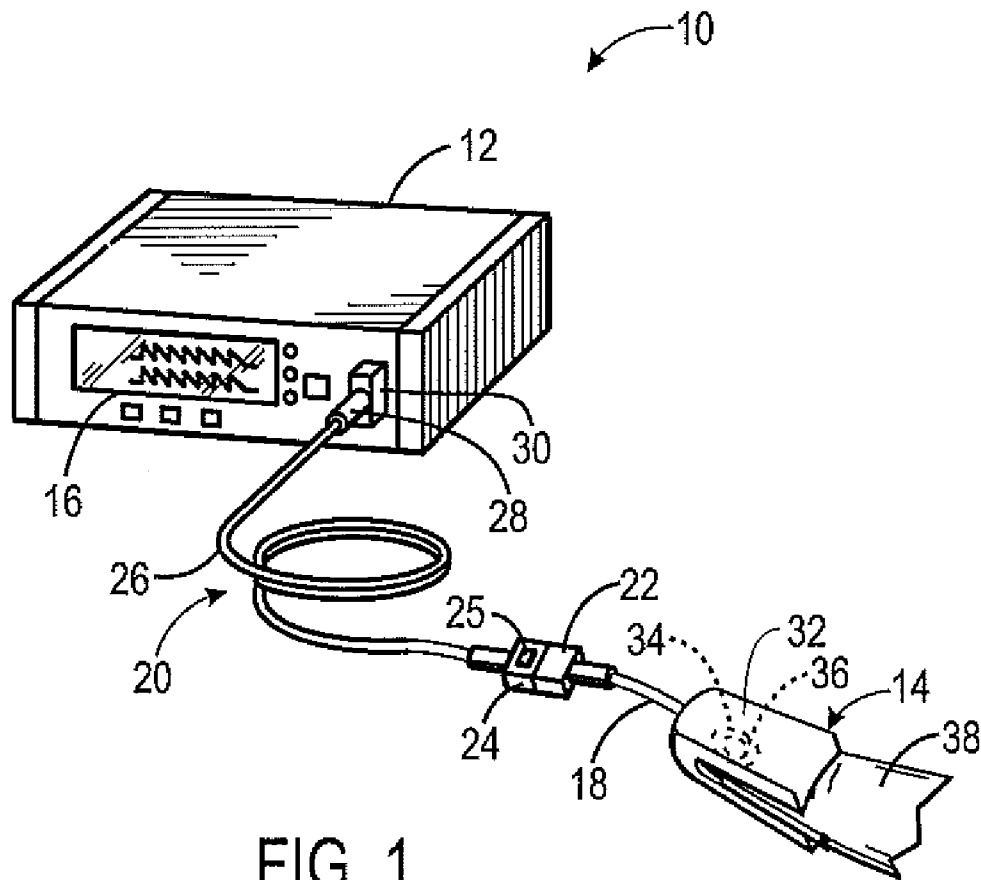


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(19) **United States**(12) **Patent Application Publication**
Lisogurski(10) **Pub. No.: US 2011/0077473 A1**(43) **Pub. Date: Mar. 31, 2011**(54) **PATIENT SENSOR INTERCOMMUNICATION
CIRCUITRY FOR A MEDICAL MONITOR**(52) **U.S. Cl. 600/301; 600/300; 174/70 R**(75) **Inventor: Daniel Lisogurski, Boulder, CO
(US)**(57) **ABSTRACT**(73) **Assignee: Nellcor Puritan Bennett LLC,
Boulder, CO (US)**(21) **Appl. No.: 12/568,944**(22) **Filed: Sep. 29, 2009****Publication Classification**(51) **Int. Cl.**
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H02G 3/00 (2006.01)

Systems, methods, and devices for intercommunication between a medical sensor and an electronic patient monitor are provided. For example, one embodiment of a system for communicably coupling a medical sensor to an electronic patient monitor may include a sensor-side communication connector and a monitor-side communication connector. The sensor-side communication connector may be capable of receiving a raw physiological measurement signal from the medical sensor, and the monitor-side communication connector may be capable of providing a digital physiological measurement signal based at least in part on the raw physiological measurement signal to the electronic patient monitor via a data link.





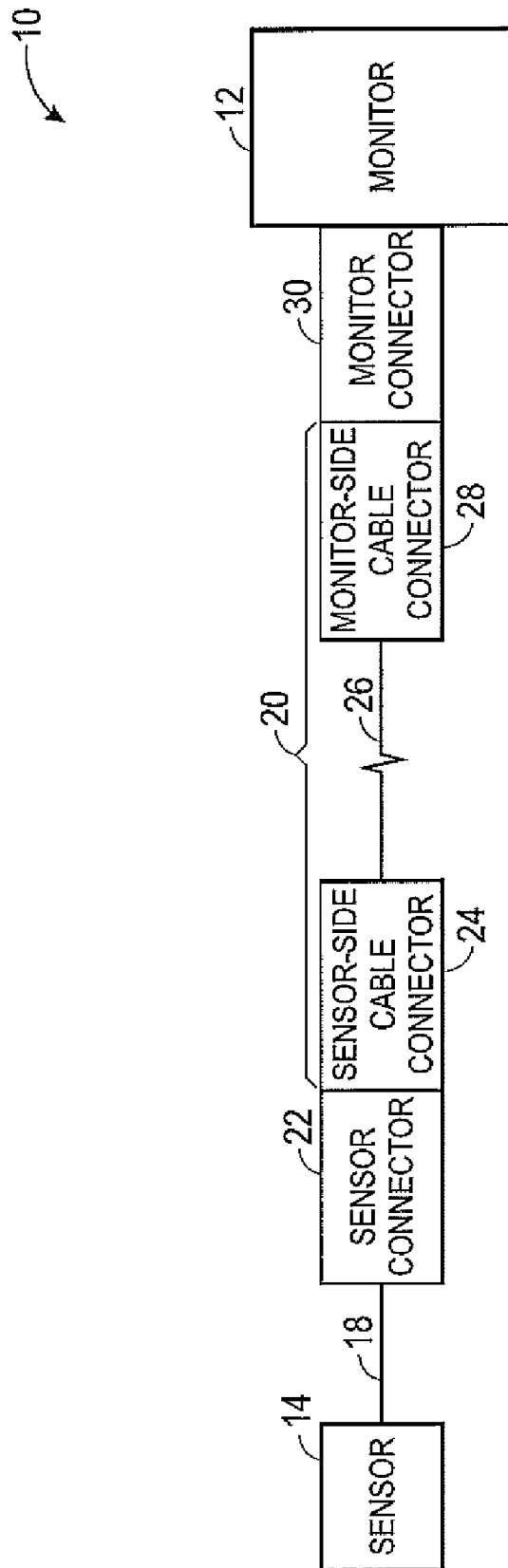


FIG. 2

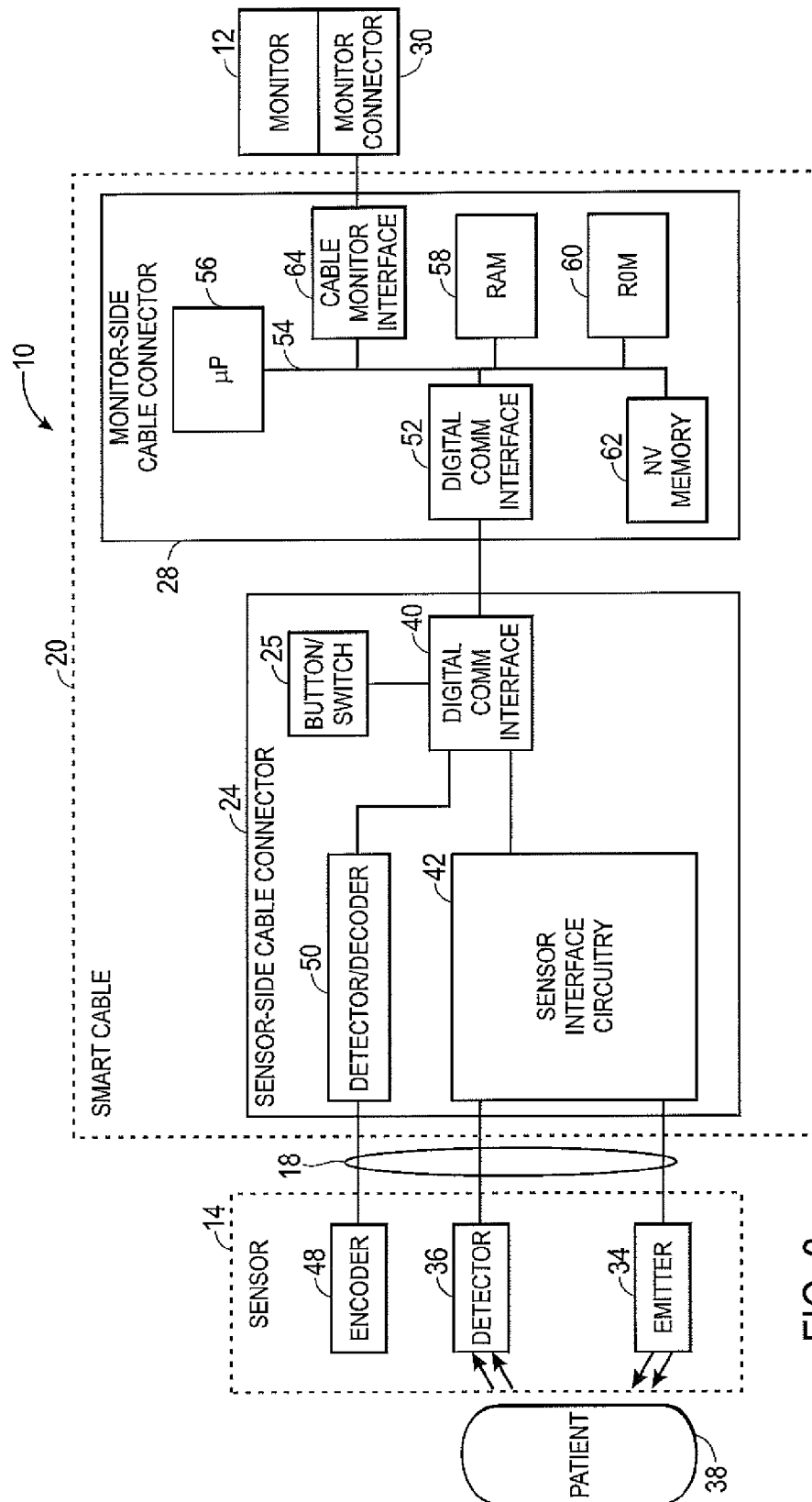


FIG. 3

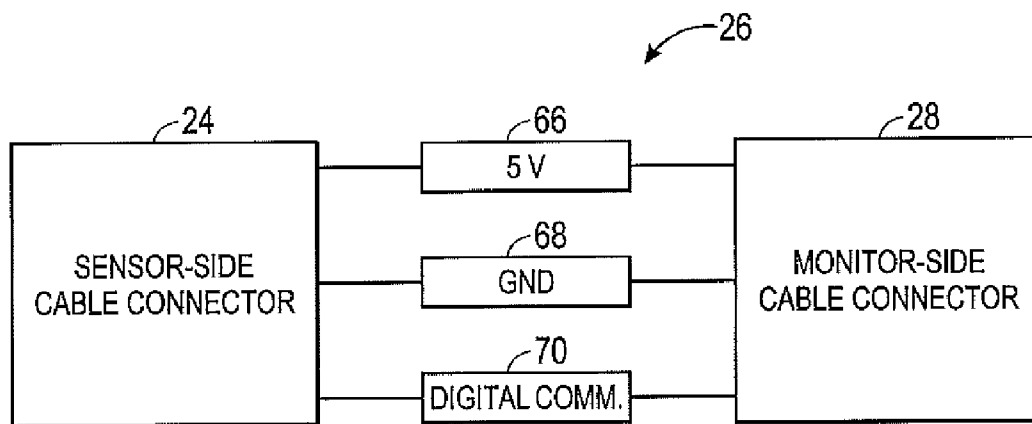


FIG. 4

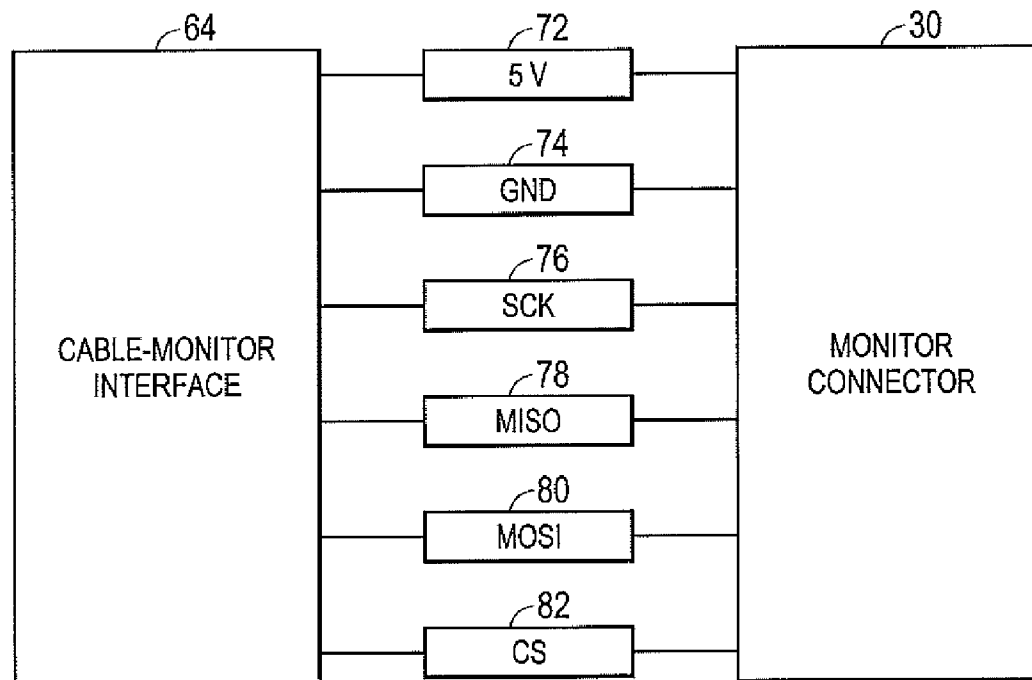


FIG. 5

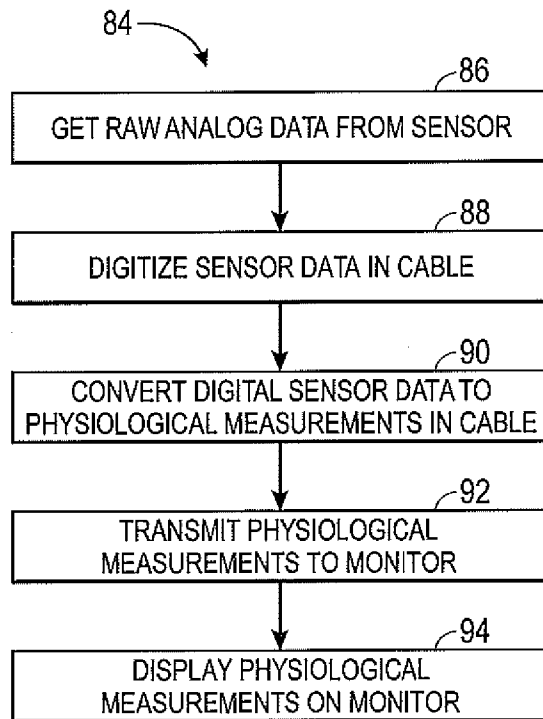


FIG. 6

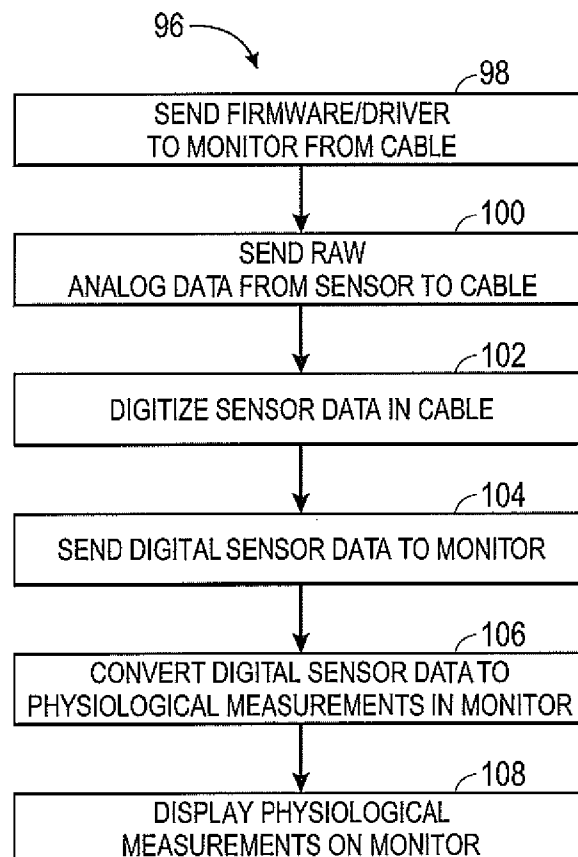


FIG. 8

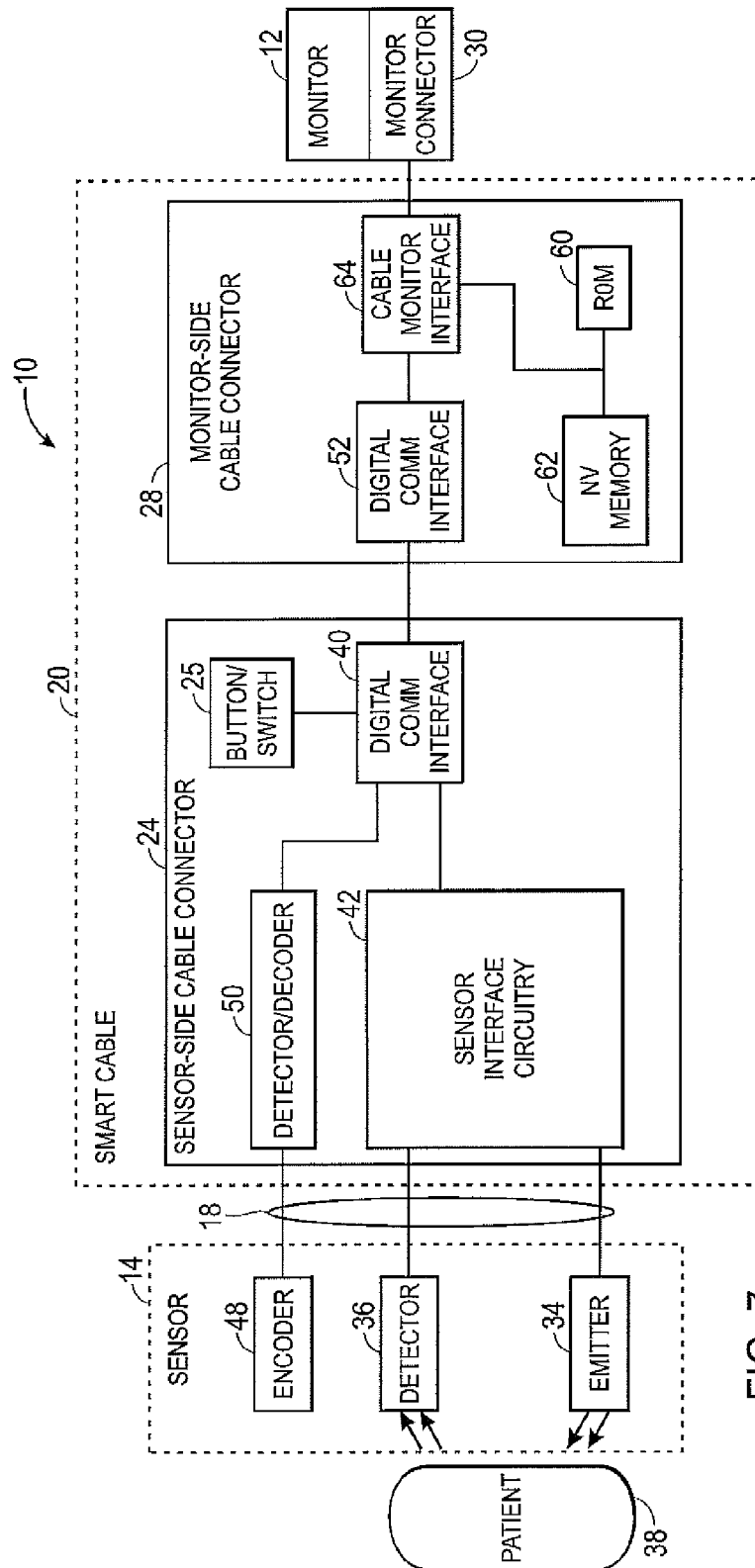


FIG. 7

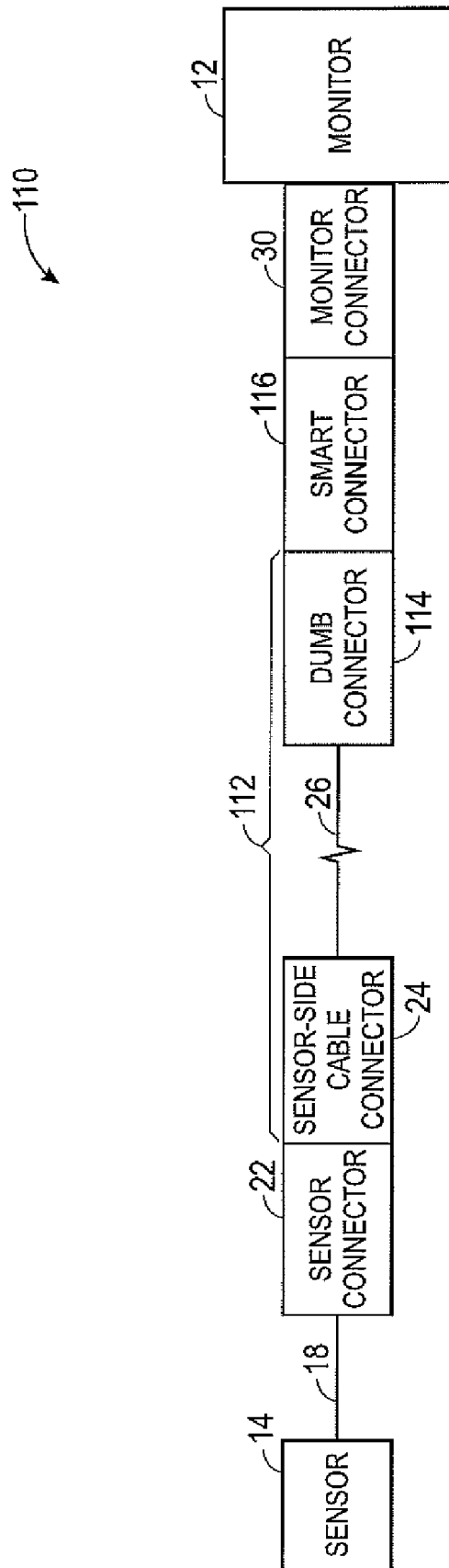


FIG. 9

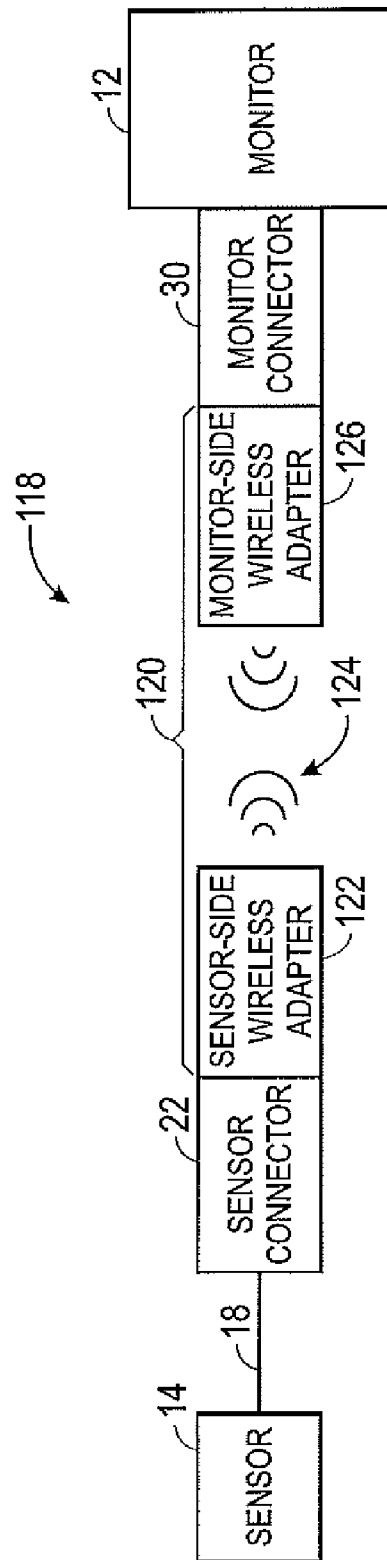


FIG. 10

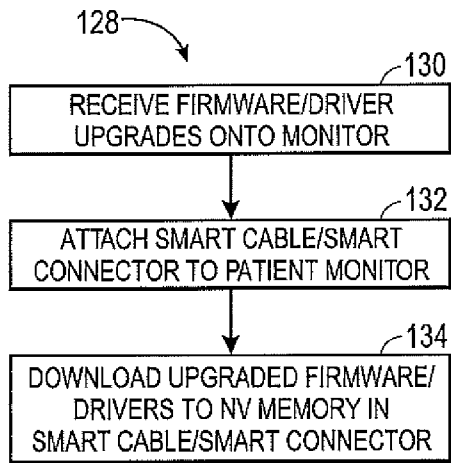


FIG. 11

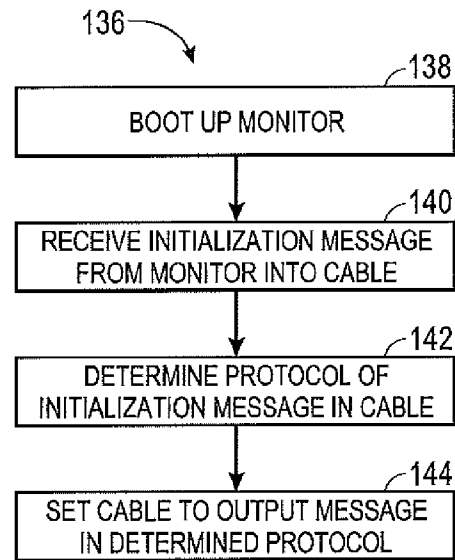


FIG. 12

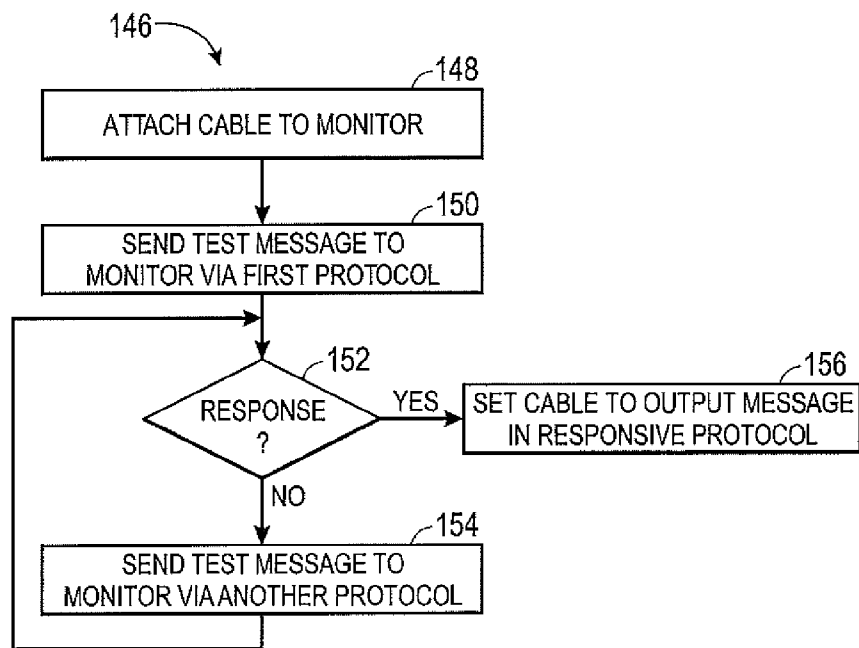
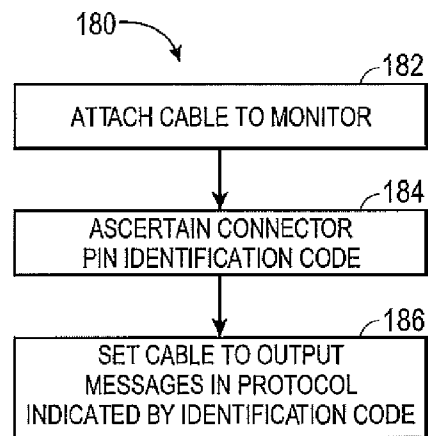
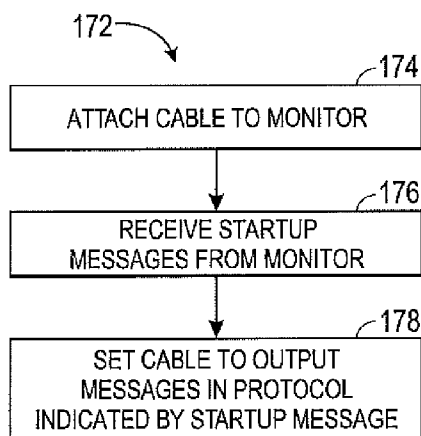
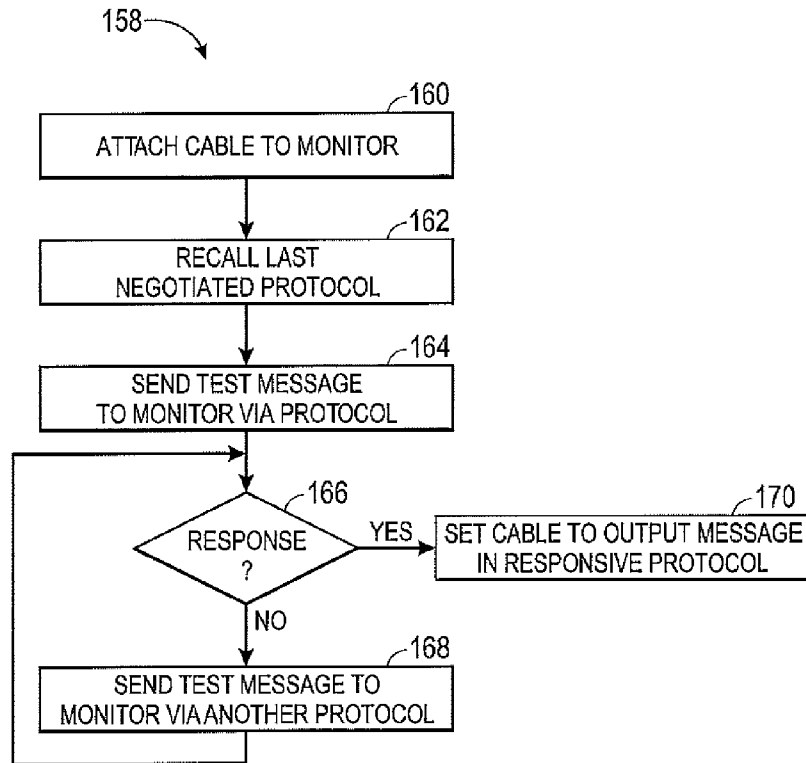


FIG. 13



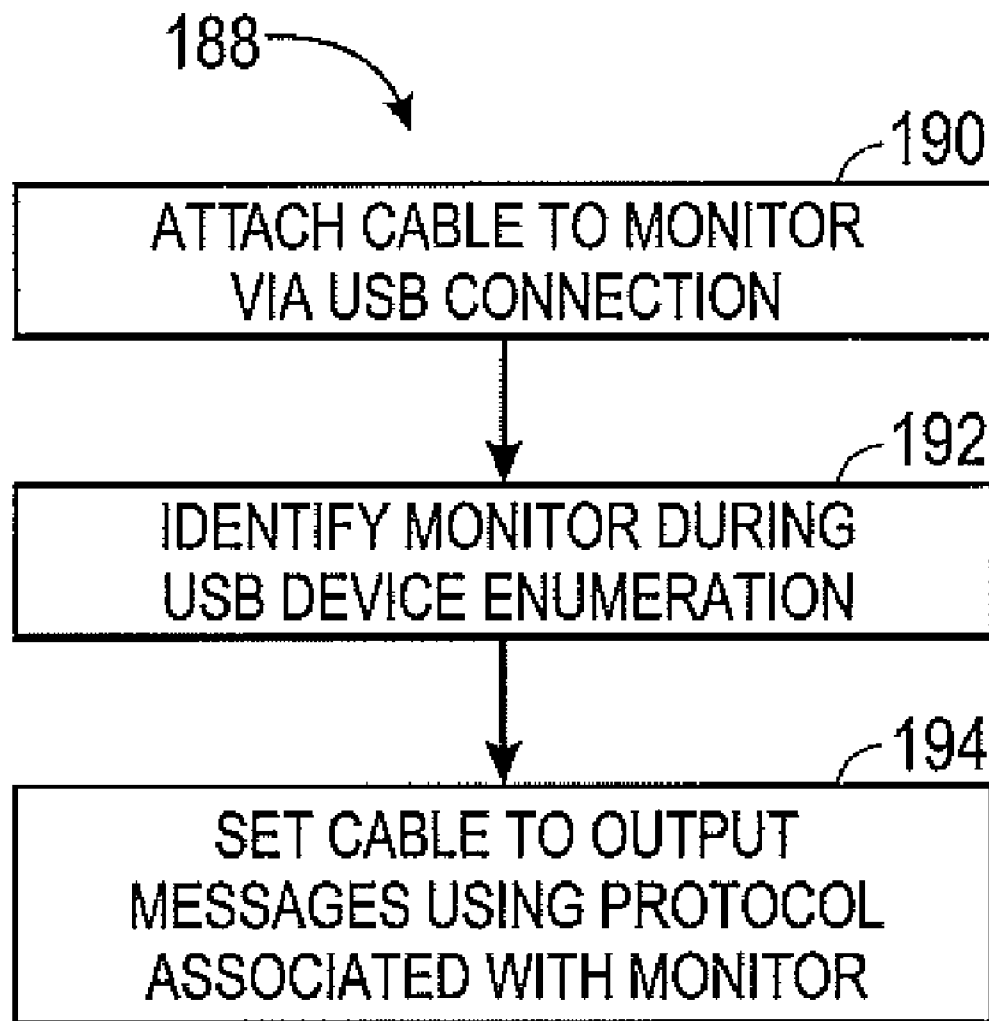


FIG. 17

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PATIENT SENSOR INTERCOMMUNICATION CIRCUITRY FOR A MEDICAL MONITOR

BACKGROUND

[0001] The presently disclosed subject matter relates generally to communicating data from a medical sensor to an electronic patient monitor and, more particularly, to communicating physiological measurements from data or instructions for obtaining physiological measurements from data to an electronic patient monitor.

[0002] This section is intended to introduce the reader to various aspects of art that may be related to various aspects of the present disclosure, which are described and/or claimed below. This discussion is believed to be helpful in providing the reader with background information to facilitate a better understanding of the various aspects of the present disclosure. Accordingly, it should be understood that these statements are to be read in this light, and not as admissions of prior art.

[0003] Electronic patient monitors may be commonly used to monitor patient parameters such as ECG, pulse oximetry, blood pressure, and/or body temperature, among other things. Multi-parameter electronic patient monitors may be expensive electronic patient monitor units that display such patient parameters from a number of supported sensor types. To accommodate sensors from a variety of manufacturers, such monitors may be designed to employ a proprietary connector for each sensor type. The sensors may be attached to the monitor via the connector through a patient cable. The patient monitor may contain a dedicated circuit that acquires data from the sensor and may include a special module that specializes in the type of sensor. For example, a multi-parameter monitor may contain an Original Equipment Manufacturer (OEM) module to determine physiological measurements from a raw measurement. By way of example, within a single electronic patient monitor, a first OEM module from a first manufacturer may receive a raw signal from a photoplethysmographic sensor, determining pulse rate and/or oxygen saturation based on the raw signal. A second OEM module from a different manufacturer may receive a raw signal from a blood pressure cuff, determining blood pressure based on the raw signal.

[0004] The OEM modules in a multi-parameter monitor may be very difficult to upgrade, as the monitor may be disassembled before the OEM module is replaced. Thus, it may be unlikely for major upgrades to a patient monitor to occur once the patient monitor has been delivered to a medical facility. Accordingly, new developments, such as improved algorithms for obtaining physiological measurements from sensor data, may not easily be included in existing patient monitors. While some upgrades involve only firmware changes, the difficulty in upgrading is especially relevant when hardware or connector changes are required. In practice, expensive monitors are seldom upgraded in the field. Typically, another device is placed next to the old monitor, resulting in cluttered hospital environments and multiple displays for the caregivers to read. It may also be difficult to base alarm decisions on multiple monitors since they typically do not communicate with each other.

SUMMARY

[0005] Certain aspects commensurate in scope with the originally claimed embodiments are set forth below. It should be understood that these aspects are presented merely to

provide the reader with a brief summary of certain forms the embodiments might take and that these aspects are not intended to limit the scope of the presently disclosed subject matter. Indeed, the embodiments may encompass a variety of aspects that may not be set forth below.

[0006] Present embodiments relate to systems, methods, and devices for intercommunicating medical sensors and electronic patient monitors. For example, one embodiment of a system for communicably coupling a medical sensor to an electronic patient monitor may include a sensor-side communication connector and a monitor-side communication connector. The sensor-side communication connector may be capable of receiving a raw physiological measurement signal from the medical sensor, and the monitor-side communication connector may be capable of providing a digital physiological measurement signal based at least in part on the raw physiological measurement signal to the electronic patient monitor via a data link.

BRIEF DESCRIPTION OF THE DRAWINGS

[0007] Advantages of the presently disclosed subject matter may become apparent upon reading the following detailed description and upon reference to the drawings in which:

[0008] FIG. 1 is a schematic diagram of a system having instructions for sensor processing in sensor-monitor communication circuitry, in accordance with an embodiment;

[0009] FIG. 2 is a block diagram of the system of FIG. 1, in accordance with an embodiment;

[0010] FIG. 3 is a more detailed block diagram of the system of FIG. 1, in accordance with an embodiment;

[0011] FIG. 4 is a block diagram of a cable connection to a medical sensor, in accordance with an embodiment;

[0012] FIG. 5 is a block diagram of a data link to a patient monitor, in accordance with an embodiment;

[0013] FIG. 6 is a flowchart describing an embodiment of a method for processing sensor data in a patient cable;

[0014] FIG. 7 is a block diagram of an alternative system of FIG. 1, in accordance with an embodiment;

[0015] FIG. 8 is a flowchart of an embodiment of a method for processing sensor data in a patient monitor based on instructions from a patient cable;

[0016] FIG. 9 is a block diagram of an alternative system for providing sensor data to a patient monitor, in accordance with an embodiment;

[0017] FIG. 10 is a block diagram describing the system of FIG. 9 in greater detail, in accordance with an embodiment;

[0018] FIG. 11 is a flowchart describing an embodiment of a method for upgrading firmware in a patient cable; and

[0019] FIGS. 12-17 are flowcharts describing embodiments of methods for determining a protocol for communication between a patient cable and a patient monitor.

DETAILED DESCRIPTION

[0020] One or more specific embodiments of the present disclosure will be described below. In an effort to provide a concise description of these embodiments, not all features of an actual implementation are described in the specification. It should be appreciated that in the development of any such actual implementation, as in any engineering or design project, numerous implementation-specific decisions must be made to achieve the developers' specific goals, such as compliance with system-related and business-related constraints, which may vary from one implementation to another. More-

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over, it should be appreciated that such a development effort might be complex and time consuming, but would nevertheless be a routine undertaking of design, fabrication, and manufacture for those of ordinary skill having the benefit of this disclosure.

[0021] Present embodiments may apply to a variety of medical sensors, including photoplethysmographic sensors, temperature sensors, respiration bands, blood pressure sensors, electrocardiogram (ECG) sensors, electroencephalogram (EEG) sensors, pulse transit time sensors, and so forth. Such sensors may communicate with an electronic patient monitor using intercommunication circuitry such as a patient cable or a wireless connection. According to embodiments disclosed herein, sensor-monitor intercommunication circuitry may include instructions for obtaining physiological measurements from raw measurements. As such, an electronic patient monitor may receive a signal over a data link using a proprietary or universal protocol from such intercommunication circuitry, despite that a specific OEM board may not necessarily be installed within the receiving monitor. For example, the patient cable may transmit messages indicating the physiological measurements or provide instructions for obtaining the physiological measurements to the monitor using a protocol that may be proprietary to the monitor.

[0022] As used in the present disclosure, “instructions” that may be used for obtaining physiological measurements may refer to any information that enables the monitor to determine physiological characteristics of a patient from data collected by a medical sensor. Such instructions may include executable code (e.g., software) written specifically for the host processor of the monitor, or written to support any suitable processor type. The instructions could include a protocol whereby the processor is instructed to load such executable code and/or data memory to an absolute or relative address in the processor’s memory. Additionally or alternatively, the instructions could include a high level script, which may be a proprietary format or an open format (e.g., Sun’s JAVA language or Perl/Unix shell scripts), which is not processor-specific and which may instruct the processor to perform certain operations on the data.

[0023] With the foregoing in mind, FIG. 1 illustrates a perspective view of an embodiment of a sensor-monitor interconnection system **10** for communicably coupling an electronic patient monitor **12** to a medical sensor **14**. Although the embodiment of the system **10** illustrated in FIG. 1 relates to photoplethysmography, the system **10** may be configured to obtain a variety of physiological measurements using a suitable medical sensor. For example, the system **10** may, additionally or alternatively, be configured to obtain a respiration rate, a patient temperature, an ECG, an EEG, a blood pressure, and/or a pulse transit time, and so forth.

[0024] The patient monitor **12** may communicate with the medical sensor **14** via a short analog cable **18** coupled to a sensor-monitor intercommunication cable **20**. The patient monitor **12** may include a display **16**, a memory, and various monitoring and control features. In certain embodiments, the patient monitor **12** may include a processor configured to receive software instructions from the sensor-monitor intercommunication cable **20**. The software instructions may be employed by the processor in the patient monitor **12** to obtain physiological measurements, such as pulse rate or blood oxygen saturation, from raw photoplethysmographic data or other raw data that has been digitized within the sensor-monitor intercommunication cable **20**. In other embodi-

ments, the patient monitor **12** may not include a processor with such capabilities, but may rather be configured to display physiological measurements, such as pulse rate or blood oxygen saturation, that have been determined within the sensor-monitor intercommunication cable **20**. For example, when the system **10** is configured for photoplethysmography, the sensor-monitor intercommunication cable **20** may include software instructions and/or capabilities for performing pulse oximetry measurements, calculations, and control algorithms, based on the sensor data received from the medical sensor **14**.

[0025] In the presently illustrated embodiment of the system **10**, the medical sensor **14** is a photoplethysmographic sensor. As should be appreciated, however, the sensor **14** may be a photoplethysmographic sensor, a temperature sensor, a respiration band, a blood pressure sensor, an arrhythmia sensor, a pulse transit time sensor, or any other suitable medical sensor. As noted above, the sensor **14** may include the short analog cable **18**. The short analog cable **18** may include a sensor connector **22** that joins to a sensor-side cable connector **24** of the sensor-monitor intercommunication cable **20**. The analog cable **18** may be of a sufficiently short length to prevent excessive interference before reaching the sensor-monitor intercommunication cable **20**. The sensor-monitor intercommunication cable **20** may include the sensor-side cable connector **24**, a monitor protocol selection button or switch **25**, intercommunication cabling **26**, and a monitor-side cable connector **28**. The monitor-side cable connector **28** may join to a monitor connector **30** with a data communication link, such as a serial peripheral interface (SPI), a universal serial bus (USB) interface, a universal asynchronous receiver/transmitter (UART) interface, a Two Wire Interface (TWI) such as I2C, or an RS232 interface, or any other suitable communication link.

[0026] As described in greater detail below, the sensor-monitor intercommunication cable **20** may communicate with the monitor **12** using a protocol understandable by the monitor **12**. Such protocols may include, for example, the Standard Host Interface Protocol (SHIP) or the Phillips Interface Protocol (PIP). The sensor-monitor intercommunication cable **20** may be preprogrammed to communicate using the protocol or may automatically select the particular protocol from among a variety of preprogrammed protocols, as described below with reference to FIGS. **12** and **13**. Additionally or alternatively, a practitioner may manually set the protocol by pressing the button or switch **25** or selecting a setting on the button or switch **25**. Thereafter, the sensor-monitor intercommunication cable **20** may communicate with the electronic patient monitor **12** and may not need to be specific to particular vendors or to particular sensors. Additionally or alternatively, the sensor-monitor intercommunication cable **20** may automatically negotiate a mutually supported protocol with the electronic patient monitor **12** or use other techniques to determine such a protocol, as generally described below with reference to FIGS. **12-17**.

[0027] A sensor assembly or body **32** of the wireless medical sensor **14** may attach to patient tissue (e.g., a patient’s finger, ear, forehead, or toe). In the illustrated embodiment, the sensor assembly **32** is configured to attach to a finger. The medical sensor **14**, illustrated in the present embodiment as a photoplethysmographic sensor, may include an emitter **34** and a detector **36**. When attached to pulsatile tissue of a patient **38**, the emitter **34** may transmit light at certain wavelengths into the tissue and the detector **36** may receive the

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light after it has passed through or is reflected by the tissue. The amount of light that passes through the tissue and other characteristics of light waves may vary in accordance with the changing amount of certain blood constituents in the tissue and the related light absorption and/or scattering. For example, the emitter **34** may emit light from two or more LEDs or other suitable light sources into the pulsatile tissue. The reflected or transmitted light may be detected with the detector **36**, such as a photodiode or photo-detector, after the light has passed through or has been reflected by the pulsatile tissue.

[0028] FIG. 2 is a simplified block diagram of the system **10** of FIG. 1. As illustrated in FIG. 2, the sensor **14** may connect to the patient monitor **12** by way of the sensor-monitor intercommunication cable **20**. In particular, the sensor connector **22** of the analog cable **18** may connect to the sensor-side cable connector **24** of the sensor-monitor intercommunication cable **20**. The sensor-side cable connector **24** may receive analog data from the medical sensor **14**, digitize the data, and transmit the digitized data to the monitor-side cable connector **28** via the digital cable **26**. One embodiment of the digital cable **26** may include minimal interconnecting cabling, which may include, for example, two power subcables and digital communication subcabling, as described below with reference to FIG. 4. It should be appreciated that the digital cable **26** may employ any suitable power cabling structures and/or techniques, and should not be understood to be limited to two power subcables.

[0029] In alternative embodiments, the sensor-side cable connector **24** may transmit the received analog data to the monitor-side cable connector **28** without first digitizing the data. With such alternative embodiments, the monitor-side cable connector **28** may instead digitize the analog data. If the sensor-side cable connector **24** does not first digitize the analog data before transmitting the data to the monitor-side cable connector **28**, additional cabling and shielding may be employed to prevent attenuation and/or interference.

[0030] The monitor-side cable connector **28** may process the digitized data to obtain a physiological measurement, transmitting the determined physiological measurement to the patient monitor **12** via the monitor connector **30**. Alternatively, the monitor-side cable connector **28** may transmit software instructions for obtaining the physiological measurements from the digitized data to the monitor **12**. Thereafter, the monitor-side cable connector **28** may transmit the digitized data to the monitor **12** via the monitor connector **30**, which may process the digitized data according to the received software instructions to obtain physiological measurements.

[0031] As described below, the monitor-side cable connector **28** may communicate with the monitor **12** via the monitor connector **30** using any suitable protocol. For example, the monitor **12** may only communicate via a single protocol, such as Phillips Interface Protocol (PIP), and the monitor-side cable connector **28** may communicate using the PIP protocol after automatically determining that messages sent to the monitor **12** be transmitted using the PIP protocol, as described below with reference to FIGS. 12-13, or after being manually set by a practitioner via the button or switch **25**.

[0032] As described further below, the monitor-side cable connector **28** may autodetect the protocol by, for example, sending a command in a given protocol and waiting for a valid response. If no valid response is returned by the monitor **12** within a given time, and the monitor-side cable connector **28**

may continue trying other protocols until a message type is found to which the monitor **12** responds. After such an initial negotiation, the monitor-side cable connector **28** may stay in the negotiated protocol until power off. Additionally or alternatively, the monitor-side cable connector **28** may store the negotiated protocol in its non-volatile memory **62** and may remember the setting at next power up (reverting to negotiations only if the saved protocol fails). Additionally or alternatively, the monitor **12** may negotiate with the monitor-side cable connector **28**. In some embodiments, the monitor **12** may identify its protocol at startup by sending a message type agreed on by several or all manufacturers of patient monitors. In some embodiments, certain connector pins may be connected to power or ground, or to specific resistors or voltages, through which the monitor-side cable connector **28** may identify the type of the monitor **12**. Also, in some embodiments, the protocol may be determined during a USB device enumeration process.

[0033] The monitor connector **30** attached to the monitor **12** may represent a communication data link capable of communicating via one or more protocols. As noted above, the monitor connector **30** may include a serial peripheral interface (SPI), a universal serial bus (USB) interface, a universal asynchronous receiver/transmitter (UART) interface, a Two Wire Interface (TWI) such as I2C, or an RS232 interface, or any other suitable communication link. One embodiment of the pinout of the monitor connector **30** is described in greater detail below with reference FIG. 5.

[0034] FIG. 3 is a more detailed block diagram of the system **10**. By way of example, embodiments of the system **10** may be implemented with any suitable medical sensor and patient monitor, such as those available from Nellcor Puritan Bennett LLC. The system **10** may include the patient monitor **12**, the sensor **14**, and the sensor-monitor intercommunication cable **20**, which may be configured to obtain, for example, a photoplethysmographic signal from patient tissue at certain predetermined wavelengths. The medical sensor **14** may be communicatively connected to the patient monitor **12** via the sensor-monitor intercommunication cable **20**. When the system **10** is operating, light from the emitter **34**, which may include one or more light emitting diodes (LEDs) of certain wavelengths, may pass into the patient **38** and be scattered and detected by the detector **36**.

[0035] Specifically, the sensor **14** may be controlled by the signals from the sensor-side cable connector **24**. A digital communication interface **40** may receive control signals from the monitor-side cable connection **28**, which may control the manner in which sensor interface circuitry **42** controls the sensor **14**. The sensor interface circuitry **42** may control the sensor **14** using any suitable pulse oximetry technique. In some embodiments, a time processing unit (TPU) may provide timing control signals to light drive circuitry. Such light drive circuitry may drive the emitter **34**, controlling when the emitter **34** is illuminated, and if multiple light sources are used, the multiplexed timing for the different light sources. The sensor interface circuitry **42** may also receive signals from the detector **36**. The signals from the detector **36** may represent raw analog data, which may be digitized by the sensor interface circuitry **42**. In some embodiments, the sensor interface circuitry **42** may include, for example, an amplifier, a filter, and an analog to digital (A/D) converter circuit. The sensor interface circuitry **42** may sample these signals at the proper time, depending upon which of multiple light sources is illuminated, if multiple light sources are used. The

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sampled signals represent digitized raw data that may be, for example, a raw 16-bit digital stream of photoplethysmographic data sampled at 100 Hz.

[0036] In an embodiment, the sensor 14 may also contain an encoder 48 that provides signals indicative of the wavelength of one or more light sources of the emitter 34, which may allow for selection of appropriate calibration coefficients for calculating a physiological parameter such as blood oxygen saturation. The encoder 48 may, for instance, be a coded resistor, EEPROM or other coding devices (such as a capacitor, inductor, PROM, RFID, parallel resonant circuits, or a colorimetric indicator) that may provide a signal related to the characteristics of the medical sensor 14 that may indicate appropriate calibration characteristics for the photoplethysmographic sensor 14. Further, the encoder 48 may include encryption coding that prevents a disposable part of the photoplethysmographic sensor 14 from being recognized by a processor 38 that is not able to decode the encryption. For example, a detector/decoder 50 may be required to translate information from the encoder 48 before it can be properly processed to obtain physiological measurements from the digitized raw data output by the sensor interface circuitry 42.

[0037] Digital data from the detector/decoder 50 and/or the sensor interface circuitry 42 may be sent to the digital communication interface 40. Additionally, if present, the button or switch 25 may provide digital information to the digital communication interface 40 indicating the particular protocol with which the sensor-monitor intercommunication cable 20 should use to communicate with the electronic patient monitor 12. The digital communication interface 40 may coordinate the transmission of the digital data to the monitor-side cable connector 28. The digital data may be transmitted over the digital cable 26 and received by another digital communication interface 52 using any suitable protocol. For example, the digital communication interfaces 40 and 52 may communicate using, for example, a serial peripheral interface (SPI), a universal serial bus (USB) interface, a universal asynchronous receiver/transmitter (UART) interface, a Two Wire Interface (TWI) such as I2C, or an RS232 interface. The digital data may be provided to a bus 54 connected to a microprocessor 56.

[0038] In various embodiments, based at least in part upon the value of the received digitized raw data corresponding to the light received by detector 36, the microprocessor 56 may calculate a physiological parameter of interest using various algorithms. These algorithms may utilize coefficients, which may be empirically determined, corresponding to, for example, the wavelengths of light used. The algorithms may store interim values and other digital data in RAM 58. The algorithms and other software instructions for obtaining a physiological measurement based on the digitized data may be stored in ROM 60 or nonvolatile storage 62, which may include, for example, Flash memory. In a two-wavelength system, the particular set of coefficients chosen for any pair of wavelength spectra may be determined by the value indicated by the encoder 48 corresponding to a particular light source provided by the emitter 34. For example, the first wavelength may be a wavelength that is highly sensitive to small quantities of deoxyhemoglobin in blood, and the second wavelength may be a complementary wavelength. Specifically, for example, such wavelengths may be produced by orange, red, infrared, green, and/or yellow LEDs. Different wavelengths may be selected based on instructions from the patient monitor 12, preferences stored in a nonvolatile storage 62. Such

instructions or preferences may be selected at the patient monitor 12 by a switch on the patient monitor 12, a keyboard, or a port providing instructions from a remote host computer. Other software or instructions for carrying out the techniques described herein may also be stored on the nonvolatile memory 62, or may be stored on the ROM 60. The physiological measurements determined in the sensor-monitor intercommunication cable 20 may be encoded in a first protocol, which may or may not be proprietary to the sensor-monitor intercommunication cable 20. As described below, the physiological measurements may be translated from the first protocol into a second protocol understandable to the monitor 12, if the monitor 12 is not capable of understanding the first protocol.

[0039] After determining physiological measurements based on the received digitized raw data, the microprocessor 56 may communicate with the monitor 12 via a cable-monitor interface 64. The cable-monitor interface 64 may transmit these physiological measurements and/or the digitized raw data to the monitor 12 via the monitor connector 30. The sensor-monitor intercommunication cable 20 may communicate using messages in a protocol understandable by the electronic patient monitor 12. The protocol may be indicated by a selection made by the button or switch 25, or may be determined automatically by the sensor-monitor intercommunication cable 20, as described below with reference to FIGS. 12 and 13. In this way, the sensor-monitor intercommunication cable 20 may not need to be specific to a manufacturer or vendor.

[0040] It should be appreciated that the configuration of the sensor-monitor intercommunication cable 20 illustrated in FIG. 3 may vary. For example, certain circuitry of the sensor-side cable connector 24 may be incorporated into the monitor-side cable connector 28. If the sensor interface circuitry 42 is incorporated into the monitor-side cable connector 28, the cable 26 may transmit analog signals rather than digital signals, and additional shielding may be used to reduce attenuation and/or interference. Similarly, certain circuitry of the monitor-side cable connector 28 may be incorporated into the sensor-side cable connector 24, such as the microprocessor 56. If the microprocessor 56 is incorporated into the sensor-side cable connector 24, the sensor-side cable connector may have the capability to determine physiological measurements from the digitized data, which may be transmitted over the digital cable 26. In certain other embodiments, all or part of the circuitry of the sensor-monitor intercommunication cable 20 may be incorporated into the medical sensor 14. However, if the medical sensor 14 is a replaceable sensor, incorporating such circuitry into the sensor 14 may be costly. Moreover, as described below with reference to FIGS. 9 and 10, circuitry with the capabilities described above may be incorporated into other intercommunication links between the sensor 14 and the electronic patient monitor. For example, the circuitry may be incorporated into a separable cable connector or dangle, or into wireless adapters for joining the medical sensor 14 and the patient monitor 12.

[0041] FIG. 4 illustrates an exemplary configuration of an embodiment of the digital cable 26 between the sensor-side cable connector 24 and the monitor-side cable connector 28. Specifically, the digital cable 26 may include power, such as a 5V supply 66 in one particular embodiment, a ground line 68, and one or more digital communication lines 70. The digital communication lines may employ any suitable protocol for intercommunication of digital data between the sen-

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sensor-side cable connector **24** and the monitor-side cable connector **28**. For example, as noted above, such protocols may include serial peripheral interface (SPI), universal serial bus (USB), universal asynchronous receiver/transmitter (UART), a Two Wire Interface (TWI) such as I2C, or RS232 protocols.

[0042] The digital cable **26** may carry signals over the longest distance of the sensor-monitor intercommunication cable **20**. By transmitting digital signals rather than analog, the digital cable **26** may not require as much shielding as a cable for transmitting an analog signal. Though some cable shielding may be employed to reduce electromagnetic emissions from the cable **26**, the digitized signals may be much less likely to be corrupted by electromagnetic noise than low amplitude sensor outputs. Moreover, digital errors over the digital cable **26** may be detected, corrected, or may trigger data re-transmission in communications between the sensor-side cable connector **24** and the monitor-side cable connector **28**.

[0043] FIG. **5** illustrates an exemplary configuration of an embodiment of the pinout interconnections between the cable-monitor interface **64** of the monitor-side cable connector **28** and the monitor connector **30**. The pinout configuration may employ any suitable protocol for intercommunication of digital data between the cable-monitor interface **64** and the monitor connector **30**. For example, as noted above, such protocols may include serial peripheral interface (SPI), universal serial bus (USB), universal asynchronous receiver/transmitter (UART), a Two Wire Interface (TWI) such as I2C, or RS232 protocols.

[0044] In the instant exemplary configuration, the pinout configuration may include a 5V line **72**, a ground line **74**, and various signal interfaces corresponding to serial peripheral interface (SPI) pins. These may include a synchronous clock (SCK) **76** pin, a master input/slave output (MISO) **78** pin, a master output/slave input (MOSI) **80** pin, and a chip select (CS) pin **82**. The SCK **76** may provide a serial clock input from the patient monitor **12** to the sensor-monitor intercommunication cable **20**. The MISO **78** may transmit synchronous serial data, such as physiological measurements determined in the monitor-side cable connector **28**, from the sensor-monitor intercommunication cable **20** to the patient monitor **12**. The MOSI **80** may transmit synchronous serial data, such as sensor control signals, from the patient monitor **12** to the sensor-monitor intercommunication cable **20**. The patient monitor **12** may use the CS **82** to elect to communicate with the sensor-monitor intercommunication cable **20**. To reduce pin count, the CS signal **82** may be omitted from the connector and tied to ground (active low) at the slave side if there is only one master and one slave on the bus. The cable may be designed such that either the monitor **12** or the sensor-monitor intercommunication cable **20** is the SPI bus master. In this way, the configuration illustrated in FIG. **5** may enable the patient monitor **12** to control a number of different sensors **14** coupled via similar SPI configurations and sensor-monitor intercommunication cables **20**.

[0045] FIG. **6** is a flowchart **84** describing an embodiment of a method for communicably coupling the medical sensor **14** to the patient monitor **12** via the sensor-monitor intercommunication cable **20**. In particular, the embodiment of the method of the flowchart **84** contemplates a sensor-monitor intercommunication cable **20** that includes the microprocessor **56**, as well as appropriate software instructions stored within the ROM **60** or the nonvolatile memory **62**. Because the sensor-monitor intercommunication cable **20** includes the

processor **56**, the patient monitor **12** need not include a processor capable of extracting physiological measurements based on data from the sensor **14**. Rather, the patient monitor **12** may require only the capability to display data received from the sensor-monitor intercommunication cable **20**. The flowchart **84** may be carried out using the embodiment of FIG. **3**, as well as embodiments with similar capabilities, such as those described below with reference to FIGS. **9** and **10**.

[0046] In a first step **86**, the sensor-monitor intercommunication cable **20** may obtain analog raw data from the sensor **14**. Depending on the medical sensor **14**, such analog data may include, for example, photoplethysmographic data, temperature data, respiration data, blood pressure data, arrhythmia data, ECG data, pulse transit time data, and so forth. By way of example, the analog raw data may be received by the sensor-side cable connector **24**. In step **88**, the raw analog data may be digitized by the sensor-monitor intercommunication cable **20** to obtain digitized raw data. If the analog raw data is a photoplethysmographic signal, the digitized raw data may be, for example, a raw 16-bit digital stream of photoplethysmographic data sampled at 100 Hz. Such digitization may take place via the sensor interface circuitry **42** in the sensor-side cable connector **24**.

[0047] In step **90**, the sensor-monitor intercommunication cable **20** may convert the digitized raw data into physiological measurements. By way of example, if the digitized raw data is photoplethysmographic data, the physiological measurements may include pulse rate, blood oxygen saturation, and/or total hemoglobin measurements. The physiological measurements may be obtained by the processing the digitized raw data using the microprocessor **56**, according to instructions stored in the ROM **60** or nonvolatile memory **62**. These physiological measurements may be transmitted to the patient monitor **12** in step **92**, and displayed on the patient monitor **12** in step **94**. The sensor-monitor intercommunication cable **20** may communicate with the electronic patient monitor **12** using messages of a protocol understandable by the electronic patient monitor **12**. The protocol may be indicated by a selection made by the button or switch **25**, or may be determined automatically by the sensor-monitor intercommunication cable **20**, as described below with reference to FIGS. **12** and **13**. In this way, the sensor-monitor intercommunication cable **20** may not need to be specific to a manufacturer or vendor.

[0048] In some embodiments, the physiological measurements obtained in step **90** may be used to determine alarm status. For example, the patient monitor **12** may indicate alarm limits for certain detectable physiological parameters to the sensor-monitor intercommunication cable **20**. If the physiological measurements obtained in step **90** exceed the alarm limits (e.g., if heart rate or SpO₂ exceed a predetermined range), the sensor-monitor intercommunication cable **20** may respond accordingly. For example, in step **92**, the sensor-monitor intercommunication cable **20** may transmit such an alarm to the patient monitor **12** in step **92**.

[0049] As noted above, the circuitry and capabilities of the sensor-monitor intercommunication cable **20** may vary. FIG. **7** illustrates an alternative embodiment of the system **10**, in which the sensor-monitor intercommunication cable **20** is capable of digitizing sensor **14** data, but lacks the ability to process the digitized data into physiological measurements on its own. In particular, the embodiment of the system **10** illustrated in FIG. **7** may be substantially identical to the embodiment of the system **10** illustrated in FIG. **3**, except that

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the monitor-side cable connector **28** may lack the microprocessor **56** and/or RAM **58**. When used with a patient monitor **12** having a suitable processor, however, the sensor-monitor intercommunication cable **20** may provide the patient monitor **12** with software instructions for obtaining such physiological measurements. Such instructions may be stored, for example, in the ROM **60** or the nonvolatile memory **62**. After receiving the software instructions from the sensor-monitor intercommunication cable **20**, the patient monitor **12** may thereafter obtain the physiological measurements based on digitized raw data received from the sensor-monitor intercommunication cable **20**.

[0050] A flowchart **96**, illustrated in FIG. **8**, describes an embodiment of a method for processing medical sensor **14** data in the patient monitor **12** using software instructions provided by the sensor-monitor intercommunication cable **20**. The embodiment of the method of the flowchart **96** may be performed using either of the embodiments of the sensor-monitor intercommunication cable **20** described in FIG. **3** or FIG. **7**, as well as the embodiments of similar circuitry with similar capabilities described below with reference to FIGS. **9** and **10**. The electronic patient monitor **12** should include a processor capable of obtaining physiological measurements from digitized raw data, when provided the appropriate software.

[0051] In a first step **98**, the sensor-monitor intercommunication cable **20** may send software instructions for obtaining physiological measurements from raw data, which may be in the form of firmware or a driver, to the electronic patient monitor **12**. Step **98** may take place, for example, when the electronic patient monitor boots up from an SPI flash memory device, or boot memory, located in the sensor-monitor intercommunication cable **20**. In step **100**, the sensor-monitor intercommunication cable **20** may receive analog raw data from the sensor **14**, in generally the same manner as described with reference to step **86** of the flowchart **84**. In step **102**, the raw analog data may be digitized by the sensor-monitor intercommunication cable **20** to obtain digitized raw data, in generally the same manner as described with reference to step **88** of the flowchart **84**.

[0052] In step **104**, the digitized raw data may be transmitted to the electronic patient monitor **12** in a particular protocol understandable to the monitor **12**. A practitioner may select the protocol via the button or switch **25**, the sensor-monitor intercommunication cable **20** may be preprogrammed to communicate using the protocol, or the sensor-monitor intercommunication cable **20** may automatically select the proper protocol, as described below with reference to FIGS. **12** and **13**. Using the firmware or driver received in step **98**, in step **106**, the monitor **12** may process the digitized raw data to obtain physiological measurements, such as pulse rate, blood oxygen saturation, and/or a measurement of total hemoglobin. In step **108**, the patient monitor **12** may display the physiological measurements on the display **16**.

[0053] FIGS. **9** and **10** represent alternative systems for intercommunication between the medical sensor **14** and the electronic patient monitor **12**. In particular, FIG. **9** illustrates a system employing the techniques described herein using an additional cable connector with memory or processing circuitry, and FIG. **10** illustrates a system employing the techniques described herein using wireless communication in place of the digital cable **26**. Turning first to FIG. **9**, a system **110** for intercommunication between the medical sensor **14** and the patient monitor **12** may include a digitizing cable **112**

coupled to the sensor connector **22** of the analog cable **18**. The digitizing cable **112** may include the sensor-side cable connector **24**, which may be configured in the manners described above. Rather than include a monitor-side cable connector **28** with memory or processing circuitry, the digitizing cable may include a dumb connector **114** that may only transfer digital signals in the manner received from the sensor-side cable connector **24**. Thus, the digitizing cable **112** may simply digitize analog raw data received from the medical sensor **14** into digital raw data.

[0054] In contrast, a smart connector **116** may include memory circuitry and/or processing circuitry for obtaining physiological measurements from digitized raw data. As such, the smart connector **116** may include substantially the same circuitry as the monitor-side cable connector **28**, as illustrated in FIG. **3** or **7**. The smart connector **116** may couple to the dumb connector **114** of the digitizing cable **112** using any suitable manner to supply power to and exchange digital communication with the digitizing cable **112**. In general, the smart connector **116** may interconnect with the dumb connector **114** in substantially the same way as the monitor-side cable connector **28** with the monitor connector **30** in the system **10**. The smart connector **116** may interconnect with the monitor connector **30** in much the same way. As such, the smart connector **116** may employ a digital communication interface such as a serial peripheral interface (SPI), a universal serial bus (USB) interface, a universal asynchronous receiver/transmitter (UART) interface, or an RS232 interface, or any other suitable communication link. In particular, the interface between the smart connector **116** and the monitor connector **30** may be a data link.

[0055] FIG. **10** illustrates a sensor-monitor intercommunication link system **118** for intercommunication between the medical sensor **14** and the patient monitor **12** that may include wireless communication circuitry. Functioning largely like the system **10**, the system **118** may include sensor-monitor wireless communication link **120** in place of the sensor-monitor intercommunication cable **20**. A sensor-side wireless adapter **122** may establish wireless communication **124** with a monitor-side wireless adapter **126** using any suitable protocol. By way of example, the protocol may include the IEEE 802.15.4 standard, and may employ, for example, the ZigBee, WirelessHART, or MiWi protocols. Additionally or alternatively, the protocol may include the Bluetooth standard or one or more of the IEEE 802.11 standards. In some embodiments, the wireless communication **124** may include optical communication, such as free space optics (FSO).

[0056] The sensor-side wireless adapter **122** and the monitor-side wireless adapter **126** may include substantially the same circuitry as the sensor-side cable connector **24** and the monitor-side cable connector **28**, respectively, except that the digital communication interfaces **40** and **52** may be configured for wireless communication and may include one or more rechargeable or replaceable batteries. The monitor-side wireless adapter **126** may couple to the monitor connector **30** in the same manner as the monitor-side cable connector **28** or the smart connector **116**. It should be understood that the wireless interface may, additionally or alternatively, form part of the monitor **12**. With such embodiments, the external connector **30** may be omitted. Also, in some embodiments, the sensor **14** may employ a single microcontroller without connector **22**, whereby the microcontroller may sample the data obtained by the sensor and may also provide the processing required for wireless communication.

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[0057] Like the system 10 discussed above, the systems 110 of FIGS. 9 and 118 of FIG. 10 may similarly enable rapid dispersion of improvements in sensor 14 processing techniques that may otherwise require an upgraded OEM module for the patient monitor 12. Thus, rather than supply a new OEM module, a vendor may supply a sensor-monitor intercommunication cable 20, a smart connector 116, or a monitor-side wireless adapter 126 with upgraded circuitry. The new sensor-monitor intercommunication cable 20, smart connector 116, or monitor-side wireless adapter 126 may be capable of processing digitized data to obtain physiological measurements or of providing such instructions to the patient monitor 12, as described above.

[0058] In certain embodiments of the systems 10, 110, or 118, the sensor-monitor intercommunication cable 20, smart connector 116, or monitor-side wireless adapter 126 may be upgradeable via software updates from a networked electronic patient monitor. FIG. 11 is a flowchart 128 illustrating one embodiment of a method for upgrading a sensor-monitor intercommunication cable 20, smart connector 116, or monitor-side wireless adapter 126. In a first step 130, software updates, such as firmware or driver updates, may be downloaded onto a networked electronic patient monitor 12. In step 132, the sensor-monitor intercommunication cable 20, smart connector 116, or monitor-side wireless adapter 126 may be attached to the electronic patient monitor 12. In step 134, the electronic patient monitor may upload the firmware or driver to the nonvolatile memory 62 of the sensor-monitor intercommunication cable 20, smart connector 116, or monitor-side wireless adapter 126. It should be understood that the software upgrades provided in the flowchart 128 may enable various additional or alternative methods for determining the physiological parameters from the digital raw data. Additionally or alternatively, the software upgrades may enable the sensor-monitor intercommunication cable 20, smart connector 116, or monitor-side wireless adapter 126 to send and/or receive messages in a particular medical messaging protocol. It should further be understood that the flowchart 128 may alternatively be carried out by connecting the sensor-monitor intercommunication cable 20, smart connector 116, or monitor-side wireless adapter 126 to a special- or general-purpose computer rather than the electronic patient monitor 12.

[0059] As noted above, the sensor-monitor intercommunication cable 20, smart connector 116, or monitor-side wireless adapter 126 may communicate with the electronic patient monitor 12 using a specific protocol, such as the Standard Host Interface Protocol (SHIP) or the Phillips Interface Protocol (PIP). The specific protocol may be selectable by a practitioner via, for example, the button or switch 25 or by programming the cable with particular firmware or drivers. Additionally or alternatively, the monitor 12, the sensor-monitor intercommunication cable 20, smart connector 116, or monitor-side wireless adapter 126 may automatically select the proper protocol for communication with the electronic patient monitor 12. FIGS. 12-17 are flowcharts representing embodiments of methods for automatically selecting such a protocol for use in the sensor-monitor intercommunication cable 20, smart connector 116, or monitor-side wireless adapter 126.

[0060] Specifically, FIG. 12 is a flowchart 136 representing an embodiment of a method for automatically selecting a protocol in the sensor-monitor intercommunication cable 20, smart connector 116, or monitor-side wireless adapter 126 based on an initialization message from the electronic patient

monitor 12. In a first step 138, the monitor 12 may be initialized. During an initialization procedure, the monitor 12 may send one or more initialization messages to each of the sensors that may be coupled to the monitor 12 in step 140. After receiving the initialization messages in step 140, in step 142, the sensor-monitor intercommunication cable 20, smart connector 116, or monitor-side wireless adapter 126 may determine the protocol in which the initialization message is encoded. The determination of step 142 may involve, for example, a comparison of initialization messages of various protocols stored in the ROM 60 or the nonvolatile memory 62, or an analysis of the syntax or semantics of the initialization message. After the protocol of the monitor 12 has been determined in step 142, the sensor-monitor intercommunication cable 20, smart connector 116, or monitor-side wireless adapter 126 may store the determined protocol in the RAM 58 or the nonvolatile storage 62. Thereafter, the sensor-monitor intercommunication cable 20, smart connector 116, or monitor-side wireless adapter 126 may communicate with the electronic patient monitor 12 using a protocol that the electronic patient monitor understands.

[0061] Similarly, FIG. 13 is a flowchart 146 representing an embodiment of a method for automatically selecting a protocol in the sensor-monitor intercommunication cable 20, smart connector 116, or monitor-side wireless adapter 126 based on the response to messages sent using a variety of protocols. In a first step 148, the sensor-monitor intercommunication cable 20, smart connector 116, or monitor-side wireless adapter 126 may be connected to the electronic patient monitor 12. The sensor-monitor intercommunication cable 20, smart connector 116, or monitor-side wireless adapter 126 may transmit a test message in a first protocol in step 150. By way of example, the first protocol may be the Standard Host Interface Protocol (SHIP).

[0062] As illustrated by a decision block 152, if the electronic patient monitor 12 does not understand the first protocol, the electronic patient monitor 12 may not respond or may respond with an error message. If so, after a timing-out period, in step 154, the sensor-monitor intercommunication cable 20, smart connector 116, or monitor-side wireless adapter 126 may send a second test message in a second protocol. By way of example, the second protocol may be the Phillips Interface Protocol (PIP).

[0063] Returning to the decision block 152, if the electronic patient monitor 12 does understand the second protocol, the electronic patient monitor 12 may respond with a message other than an error message. If so, in step 156, the sensor-monitor intercommunication cable 20, smart connector 116, or monitor-side wireless adapter 126 may store the protocol that achieved a non-error message response from the monitor 12 in the RAM 58 or nonvolatile storage 62. On the other hand, if the electronic patient monitor 12 does not understand the second protocol, the sensor-monitor intercommunication cable 20, smart connector 116, or monitor-side wireless adapter 126 may continue to send test messages in various protocols, which may be preprogrammed in the ROM 60 or nonvolatile storage 62, until the electronic patient monitor 12 responds favorably.

[0064] The sensor-monitor intercommunication cable 20, smart connector 116, or monitor-side wireless adapter 126 may discern whether a response from the electronic patient monitor 12 is valid in any suitable manner. For example, the sensor-monitor intercommunication cable 20, smart connector 116, or monitor-side wireless adapter 126 may send test

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messages in every protocol preprogrammed in ROM 60 or nonvolatile storage 62 and store the responses from the monitor 12. If certain responses differ from other responses, and particularly if one response is different from all other responses, the sensor-monitor intercommunication cable 20, smart connector 116, or monitor-side wireless adapter 126 may determine that the other responses are error messages and the different response(s) is a normal response. Alternatively, the sensor-monitor intercommunication cable 20, smart connector 116, or monitor-side wireless adapter 126 may compare the responses as they arrive to stored error messages in the ROM 60 or nonvolatile storage 62 to determine what responses from the electronic patient monitor 12 are normal responses indicating that the monitor 12 understands the protocol of the test message and which responses are error messages indicating that the monitor 12 does not understand the protocol of the test message. In some embodiments, the sensor-monitor intercommunication cable 20 may send an intentionally errored message to the monitor 12. The protocol of the monitor 12 can be narrowed down based on whether the monitor 12 replies to errored messages and/or the format of the response. Certain protocols (e.g. SHIP) may have one or more SYNC byte(s) to start a message and cyclic redundancy check (CRC) for error checking, which may reduce ambiguity in determining whether a message from the monitor 12 is valid.

[0065] FIG. 14 is a flowchart 158 representing an embodiment of a method for automatically selecting a protocol in the sensor-monitor intercommunication cable 20, smart connector 116, or monitor-side wireless adapter 126 based on the response to messages sent using a variety of protocols. In a first step 160, the sensor-monitor intercommunication cable 20, smart connector 116, or monitor-side wireless adapter 126 may be connected to the electronic patient monitor 12. In step 162, the sensor-monitor intercommunication cable 20, smart connector 116, or monitor-side wireless adapter 126 may recall the most recently negotiated protocol, which may have been stored in non-volatile storage 62. The sensor-monitor intercommunication cable 20, smart connector 116, or monitor-side wireless adapter 126 may transmit a test message in the recalled protocol in step 164. Thereafter, decision block 166 and steps 168 and 170 may take place in substantially the same manner as decision block 152 and steps 154 and 156 of the flowchart 146 of FIG. 13.

[0066] FIG. 15 is a flowchart 172 representing an embodiment of a method for automatically selecting a protocol in the sensor-monitor intercommunication cable 20, smart connector 116, or monitor-side wireless adapter 126 based on a configuration message from the patient monitor 12. In a first step 174, the sensor-monitor intercommunication cable 20, smart connector 116, or monitor-side wireless adapter 126 may be connected to the electronic patient monitor 12. In step 176, the patient monitor 12 may provide a configuration message. The configuration message may be provided in a format that was previously agreed upon by many or all manufacturers of patient monitors 12. The message may indicate various information regarding the operation of the patient monitor 12, including the communication protocol employed by the patient monitor 12. In step 178, the sensor-monitor intercommunication cable 20, smart connector 116, or monitor-side wireless adapter 126 may store the protocol indicated by the configuration message from the monitor 12 in the RAM 58 or nonvolatile storage 62.

[0067] FIG. 16 is a flowchart 180 representing an embodiment of a method for automatically selecting a protocol in the sensor-monitor intercommunication cable 20, smart connector 116, or monitor-side wireless adapter 126 based on a connector 18 pin identification code from the patient monitor 12. In a first step 182, the sensor-monitor intercommunication cable 20, smart connector 116, or monitor-side wireless adapter 126 may be connected to the electronic patient monitor 12. In some embodiments, certain pins of the connector 18 of the patient monitor 12 may be connected to power or ground, or to specific resistors or voltages, which may uniquely identify the type of the patient monitor 12 or the protocol employed by the patient monitor 12. For such embodiments, in step 184, sensor-monitor intercommunication cable 20, smart connector 116, or monitor-side wireless adapter 126 may detect such a connector 18 pin identification code that may identify the communication protocol employed by the patient monitor 12. In step 186, the sensor-monitor intercommunication cable 20, smart connector 116, or monitor-side wireless adapter 126 may store the protocol indicated by the connector 18 pin identification code from the monitor 12 in the RAM 58 or nonvolatile storage 62.

[0068] FIG. 17 is a flowchart 188 representing an embodiment of a method for automatically selecting a protocol in the sensor-monitor intercommunication cable 20, smart connector 116, or monitor-side wireless adapter 126 based on a USB device enumeration process. As noted above, in some embodiments, the sensor-monitor intercommunication cable 20, smart connector 116, or monitor-side wireless adapter 126 may be connected to the electronic patient monitor 12 via a USB connection. Such embodiments, as noted step 190, may be attached to the patient monitor 12. A USB device enumeration process may ensue. In step 192, based on information retrieved from the patient monitor 12 during the USB device enumeration process, the type of patient monitor 12 may be identified. With knowledge of the type of the patient monitor 12, the sensor-monitor intercommunication cable 20, smart connector 116, or monitor-side wireless adapter 126 may identify the protocol employed by such type of patient monitor 12. Thus, in step 186, the sensor-monitor intercommunication cable 20, smart connector 116, or monitor-side wireless adapter 126 may store the protocol indicated by the USB device enumeration process into the RAM 58 or non-volatile storage 62.

[0069] While many of the methods for determining the communication protocol generally have been described as taking place in the sensor-monitor intercommunication cable 20, smart connector 116, or monitor-side wireless adapter 126, it should be understood that such methods may, additionally or alternatively, take place in the patient monitor 12. That is, the patient monitor 12 may perform those actions ascribed to the sensor-monitor intercommunication cable 20, smart connector 116, or monitor-side wireless adapter 126, to determine which communication protocol to employ.

[0070] In alternative embodiments, the sensor-monitor intercommunication cable 20, smart connector 116, or monitor-side wireless adapter 126 may communicate with the electronic patient monitor 12 in other ways. For example, rather than communicate using a single protocol, the sensor-monitor intercommunication cable 20, smart connector 116, or monitor-side wireless adapter 126 may communicate a single message using several protocols, and the electronic patient monitor 12 may disregard messages not encoded in the protocol it understands. Additionally or alternatively, the

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sensor-monitor intercommunication cable **20**, smart connector **116**, or monitor-side wireless adapter **126** may output information in a universal protocol not specific to a particular vendor, or may output raw information using a protocol such as serial peripheral interface (SPI) or universal serial bus (USB).

[0071] While the embodiments set forth in the present disclosure may be susceptible to various modifications and alternative forms, specific embodiments have been shown by way of example in the drawings and have been described in detail herein. However, it should be understood that the disclosure is not intended to be limited to the particular forms disclosed. The disclosure is to cover all modifications, equivalents, and alternatives falling within the spirit and scope of the disclosure as defined by the following appended claims.

What is claimed is:

1. A system for communicably coupling a medical sensor to an electronic patient monitor, comprising:

- a sensor-side communication connector capable of receiving a raw physiological measurement signal from the medical sensor; and
- a monitor-side communication connector capable of providing a digital physiological measurement signal based at least in part on the raw physiological measurement signal to the electronic patient monitor via a data link.

2. The system of claim **1**, wherein the sensor-side communication connector is capable of receiving the raw physiological measurement signal from the medical sensor, wherein the raw physiological measurement signal comprises a photoplethysmographic signal; a respiration signal; a temperature signal; an electrocardiogram signal; an electroencephalogram signal; a blood pressure signal; or a pulse transit time signal; or any combination thereof.

3. The system of claim **1**, wherein the sensor-side communication connector is capable of receiving the raw physiological measurement signal, wherein the raw physiological measurement signal comprises an analog signal, wherein the sensor-side communication connector is capable of digitizing the raw physiological measurement signal to obtain a digitized raw physiological measurement signal, and wherein the monitor-side communication connector is capable of receiving the digitized raw physiological measurement signal from the sensor-side communication connector.

4. The system of claim **1**, wherein the sensor-side communication connector is capable of determining a physiological parameter based at least in part on the raw physiological measurement signal, and wherein the digital physiological measurement signal comprises the determined physiological parameter.

5. The system of claim **1**, wherein the digital physiological measurement signal comprises the raw physiological measurement signal in digital form and instructions for obtaining a physiological parameter based at least in part on the raw physiological measurement signal in digital form.

6. The system of claim **1**, wherein the monitor-side communication connector is capable of determining a physiological parameter based at least in part on the raw physiological measurement signal, and wherein the digital physiological measurement signal comprises the determined physiological parameter.

7. The system of claim **1**, wherein the digital physiological measurement signal comprises an indication of an alarm.

8. The system of claim **1**, wherein the data link comprises a serial peripheral interface; a universal serial bus interface; a universal asynchronous receiver/transmitter interface; a two wire interface; an I2C interface; or an RS232 interface; or any combination thereof.

9. The system of claim **1**, comprising interconnection cabling capable of providing digital intercommunication between the sensor-side cable connector and the monitor-side cable connector.

10. The system of claim **1**, wherein the sensor-side communication connector and the monitor-side communication connector are capable of wireless intercommunication.

11. A system comprising:

- a medical sensor capable of obtaining a raw signal from a patient;
- an electronic patient monitor capable of displaying physiological measurements; and
- sensor-monitor intercommunication circuitry capable of physically coupling to the medical sensor and to the electronic patient monitor, receiving the raw signal from the medical sensor, determining the physiological measurements based at least in part on the raw signal, and providing the physiological measurements to the electronic patient monitor via a protocol decodable to the electronic patient monitor.

12. The system of claim **11**, wherein the medical sensor comprises a photoplethysmographic sensor; a respiration band; a temperature sensor; a blood pressure sensor; an electrocardiogram sensor; an electroencephalogram sensor; or a pulse transit time sensor; or any combination thereof.

13. The system of claim **11**, wherein the electronic patient monitor is unable to determine the physiological measurements without the sensor-monitor intercommunication circuitry.

14. The system of claim **11**, wherein the sensor-monitor intercommunication circuitry comprises a patient cable; a separable patient cable connector; or wireless communication circuitry; or any combination thereof.

15. A patient cable for communicably coupling a medical sensor to an electronic patient monitor comprising:

- a first cable connector capable of receiving an analog signal from the medical sensor;
- a second cable connector capable of transmitting a digital monitor signal to the electronic patient monitor via a protocol decodable by the electronic patient monitor;
- interconnection cabling between the first cable connector and the second cable connector; and
- circuitry disposed in the first cable connector, the second cable connector, or the interconnection cabling, or any combination thereof, that is capable of digitizing the analog signal to obtain a digital signal and capable of determining the digital monitor signal based at least in part on the digital signal.

16. The patient cable of claim **15**, comprising a user input structure capable of indicating the protocol decodable by the electronic patient monitor to the patient cable.

17. The patient cable of claim **15**, comprising circuitry disposed in the first cable connector, the second cable connector, or the interconnection cabling, or any combination thereof, that is capable of determining the protocol decodable by the electronic patient monitor.

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18. The patient cable of claim **17**, wherein the circuitry capable of determining the protocol decodable by the electronic patient monitor is capable of determining the protocol by receiving and analyzing an initialization message or a configuration message, or a combination thereof, from the electronic patient monitor.

19. The patient cable of claim **17**, wherein the circuitry capable of determining the protocol decodable by the electronic patient monitor is capable of determining the protocol by transmitting one or more test messages in one or more different protocols to the electronic patient monitor until the electronic patient monitor responds favorably.

20. The patient cable of claim **17**, wherein the circuitry capable of determining the protocol decodable by the electronic patient monitor is capable of determining the protocol based at least in part on a connector pin identification code associated with the electronic patient monitor.

21. The patient cable of claim **17**, wherein the circuitry capable of determining the protocol decodable by the electronic patient monitor is capable of determining the protocol based at least in part on an indication of a type of the electronic patient monitor indicated by a universal serial bus device enumeration process.

22. A patient cable for communicably coupling a medical sensor to an electronic patient monitor comprising:

a first cable connector capable of receiving a signal from the medical sensor;

a second cable connector capable of transmitting software instructions for obtaining a physiological measurement from a digital monitor signal to the electronic patient monitor and capable of transmitting the digital monitor signal to the electronic patient monitor via a protocol decodable by the electronic patient monitor;

interconnection cabling between the first cable connector and the second cable connector; and

circuitry disposed in the first cable connector, the second cable connector, or the interconnection cabling, or any combination thereof, that is capable of determining the digital monitor signal based at least in part on the signal.

23. The patient cable of claim **22**, wherein the second cable connector is capable of transmitting the software instructions when the electronic patient monitor is initialized.

24. The patient cable of claim **22**, wherein the second cable connector comprises a serial peripheral interface boot memory device having the software instructions stored therein.

* * * * *

EXHIBIT 16



US 20120226117A1

(19) **United States**(12) **Patent Application Publication****Lamego et al.**(10) **Pub. No.: US 2012/0226117 A1**(43) **Pub. Date: Sep. 6, 2012**

(54) **HANDHELD PROCESSING DEVICE
INCLUDING MEDICAL APPLICATIONS FOR
MINIMALLY AND NON INVASIVE GLUCOSE
MEASUREMENTS**

Related U.S. Application Data

(60) Provisional application No. 61/418,807, filed on Dec. 1, 2010, provisional application No. 61/422,284, filed on Dec. 13, 2010.

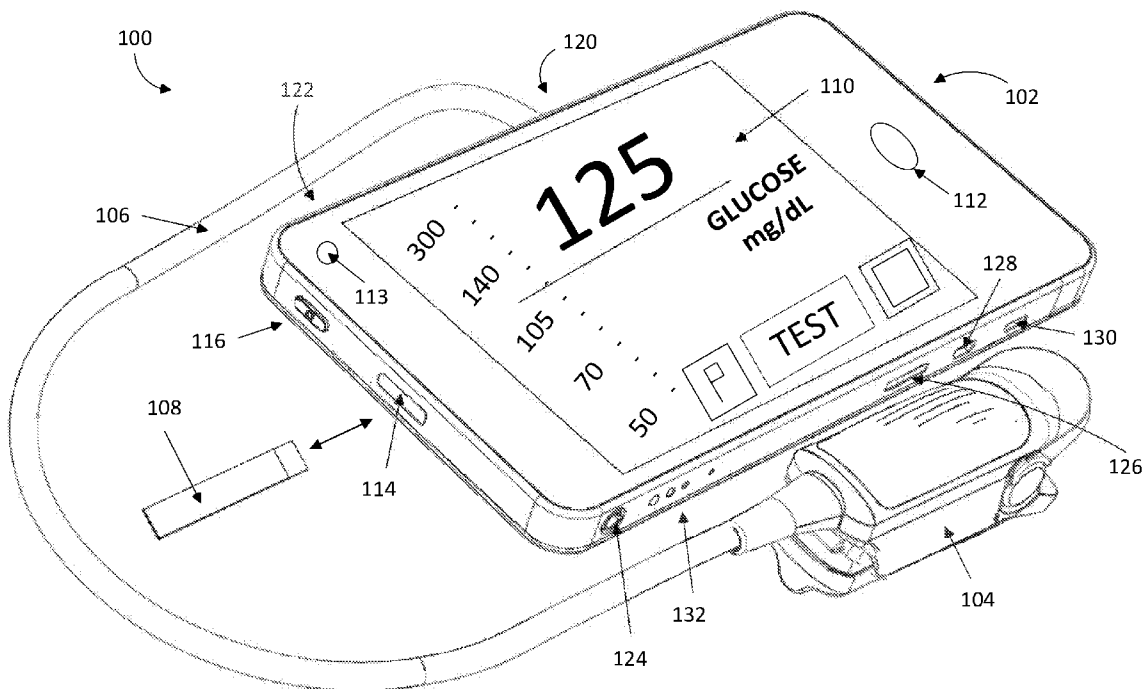
(76) Inventors: **Marcelo M. Lamego**, Coto De Caza, CA (US); **Massi Joe E. Kiani**, Laguna Niguel, CA (US); **Jeroen Poeze**, Mission Viejo, CA (US); **Cristiano Dalvi**, Irvine, CA (US); **Sean Merritt**, Lake Forest, CA (US); **Hung Vo**, Garden Grove, CA (US); **Gregory A. Olsen**, Trabuco Canyon, CA (US); **Ferdyan Lesmana**, Irvine, CA (US)

Publication Classification

(51) **Int. Cl.**
A61B 5/1455 (2006.01)
(52) **U.S. Cl.** **600/316**

(57) **ABSTRACT**

The present disclosure includes a handheld processing device including medical applications for minimally and noninvasive glucose measurements. In an embodiment, the device creates a patient specific calibration using a measurement protocol of minimally invasive measurements and noninvasive measurements, eventually creating a patient specific non-invasive glucometer. Additionally, embodiments of the present disclosure provide for the processing device to execute medical applications and non-medical applications.

(21) Appl. No.: **13/308,461**(22) Filed: **Nov. 30, 2011**

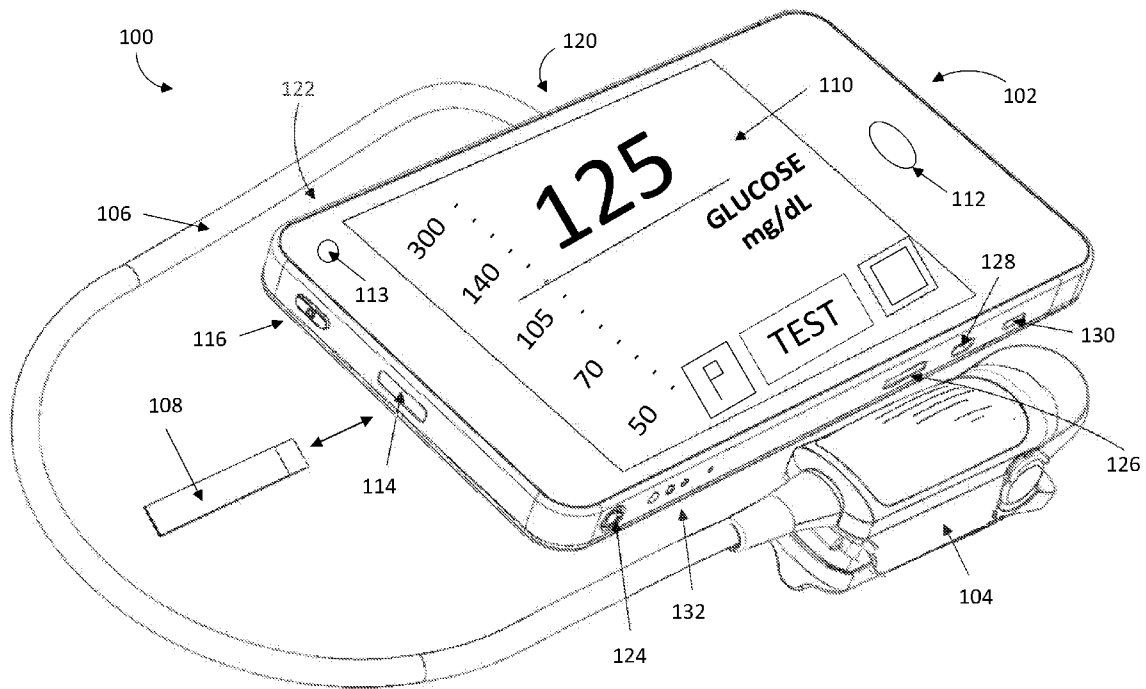
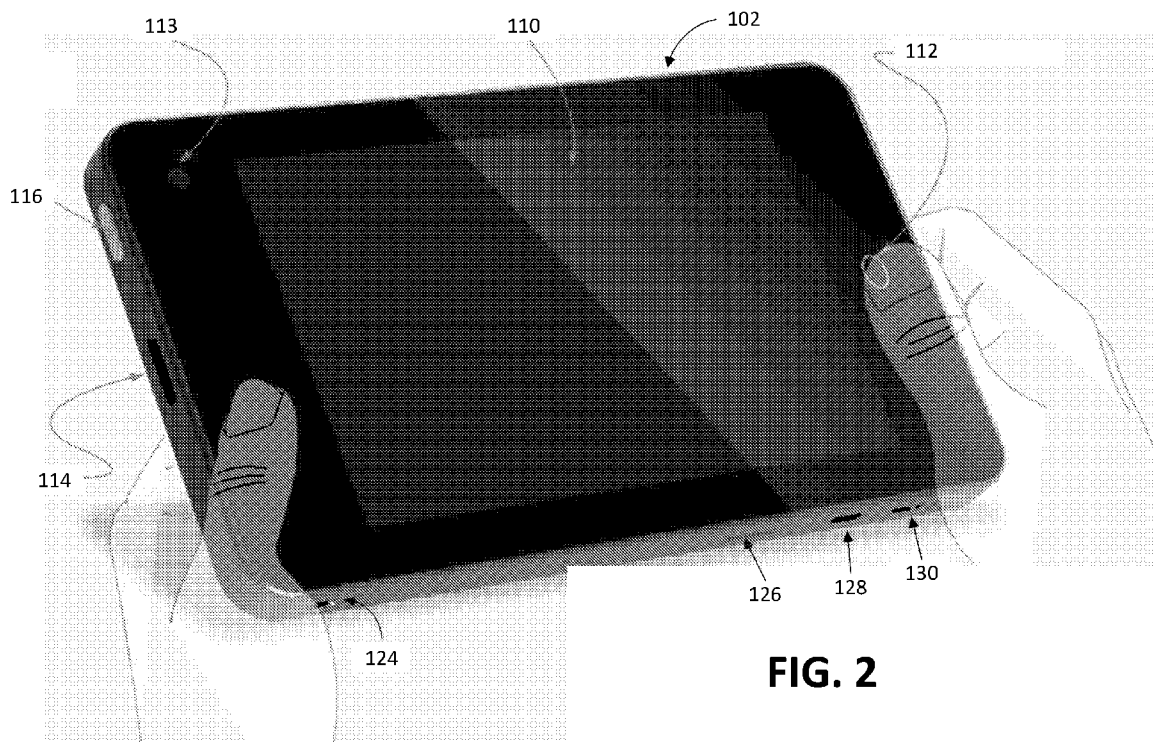
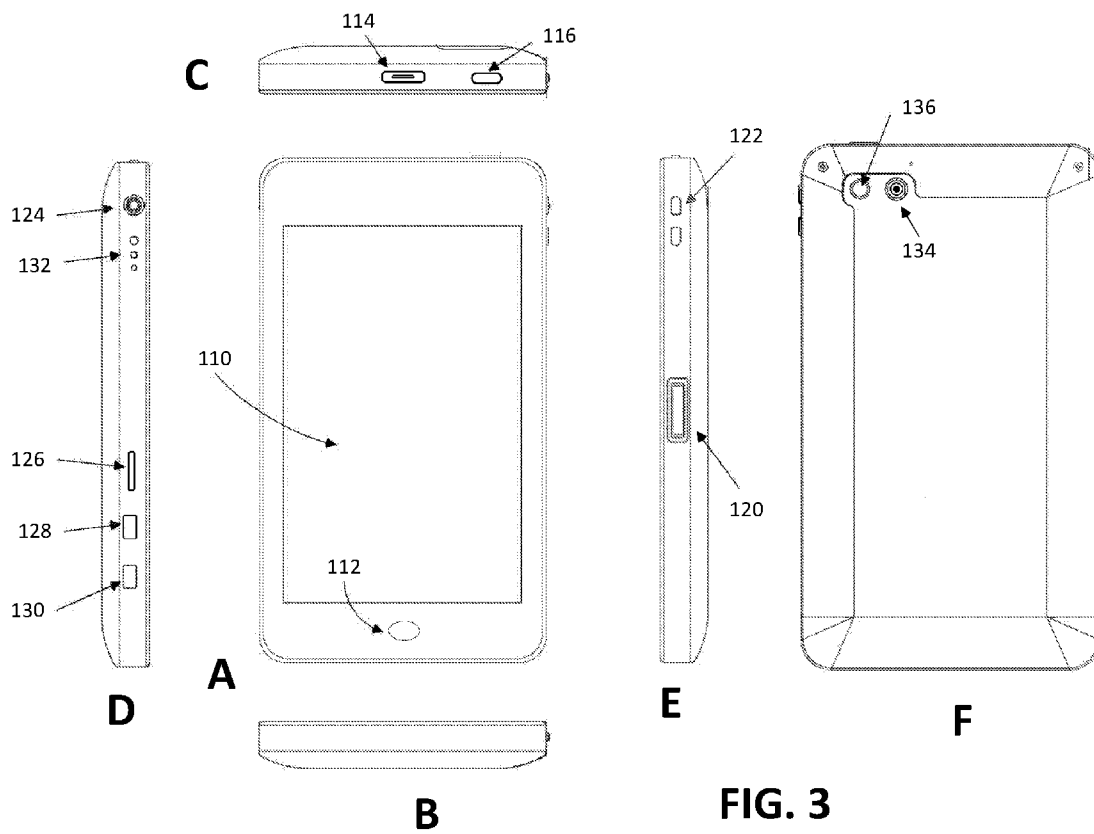


FIG. 1





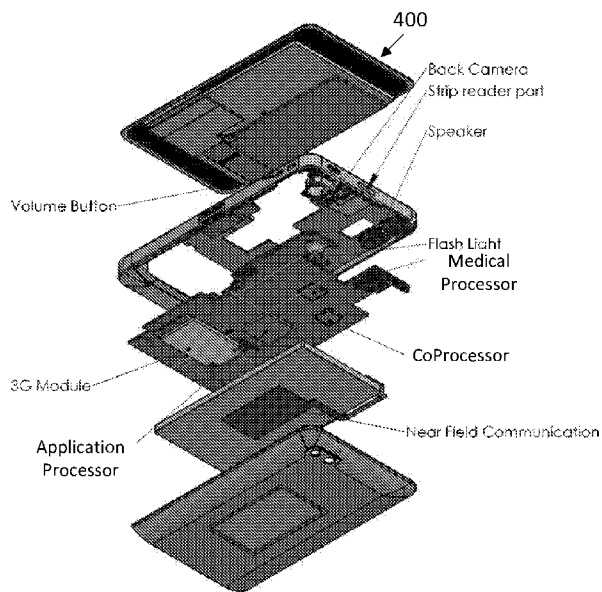


FIG. 4A

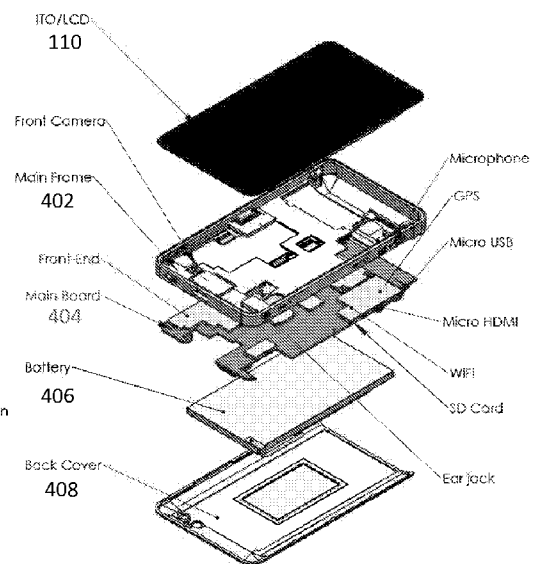
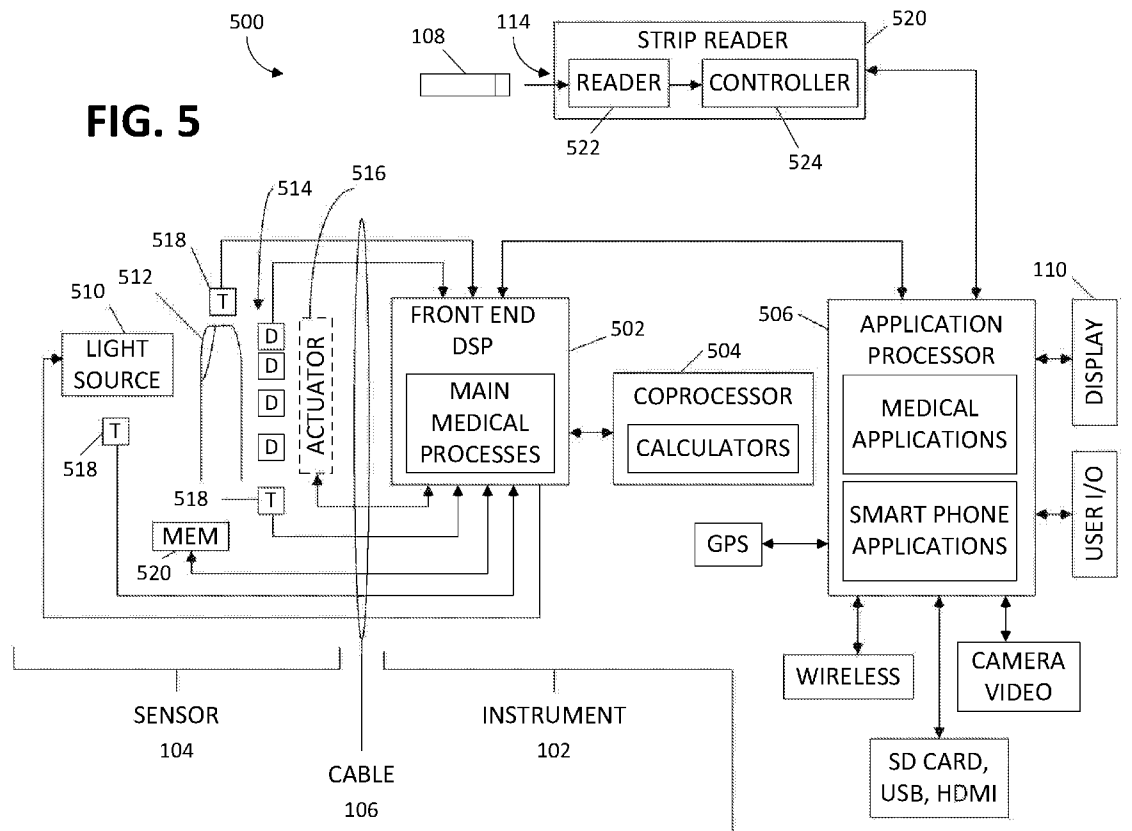
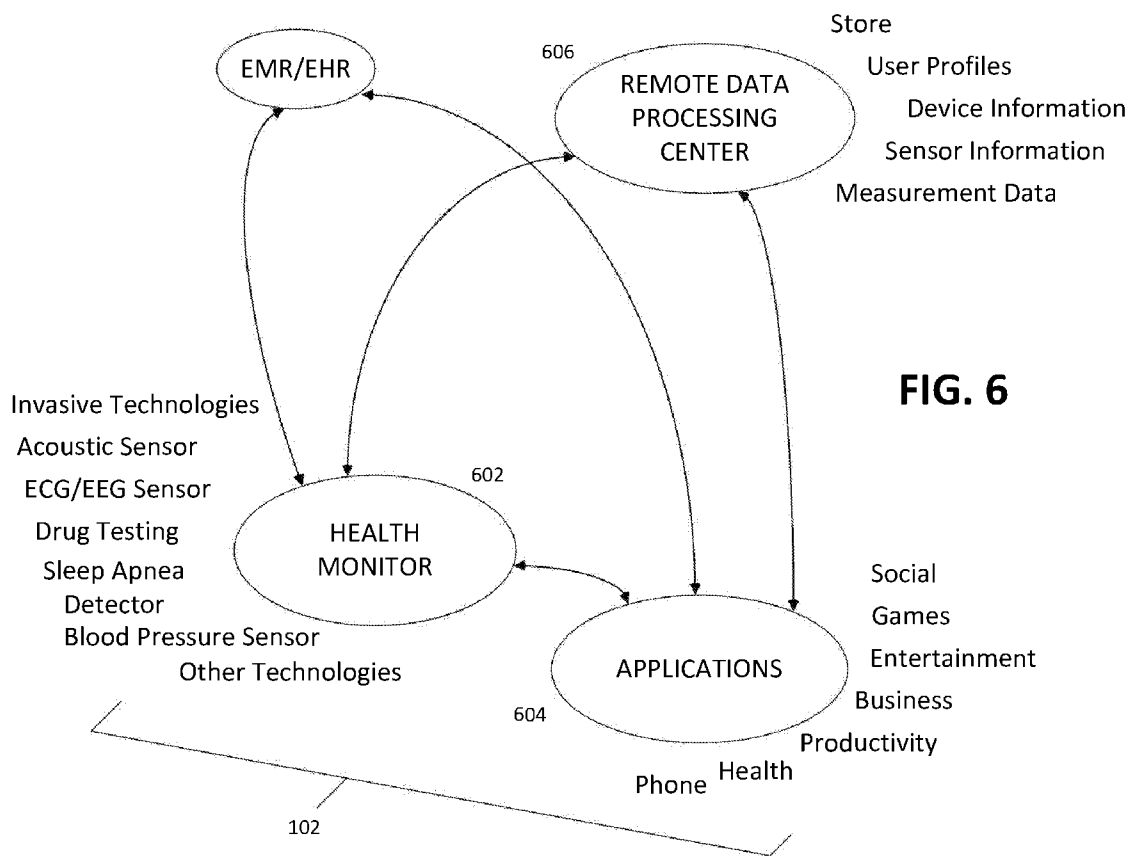


FIG. 4B





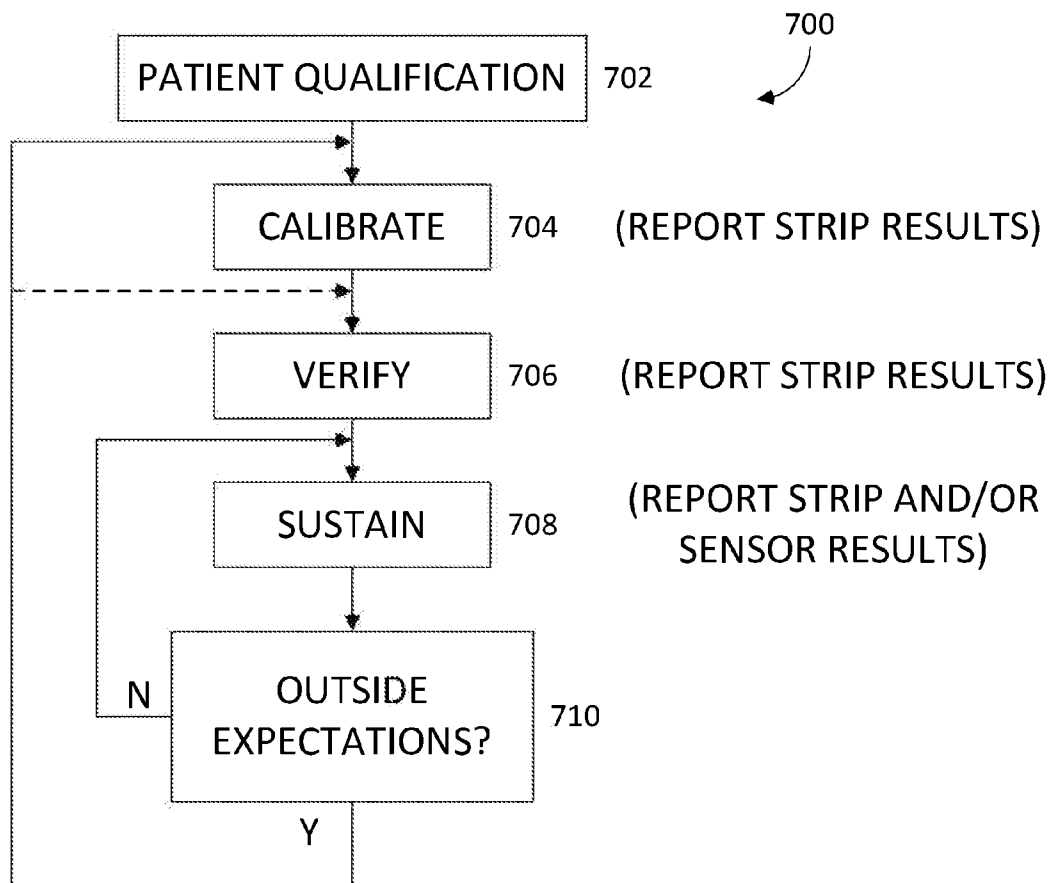


FIG. 7

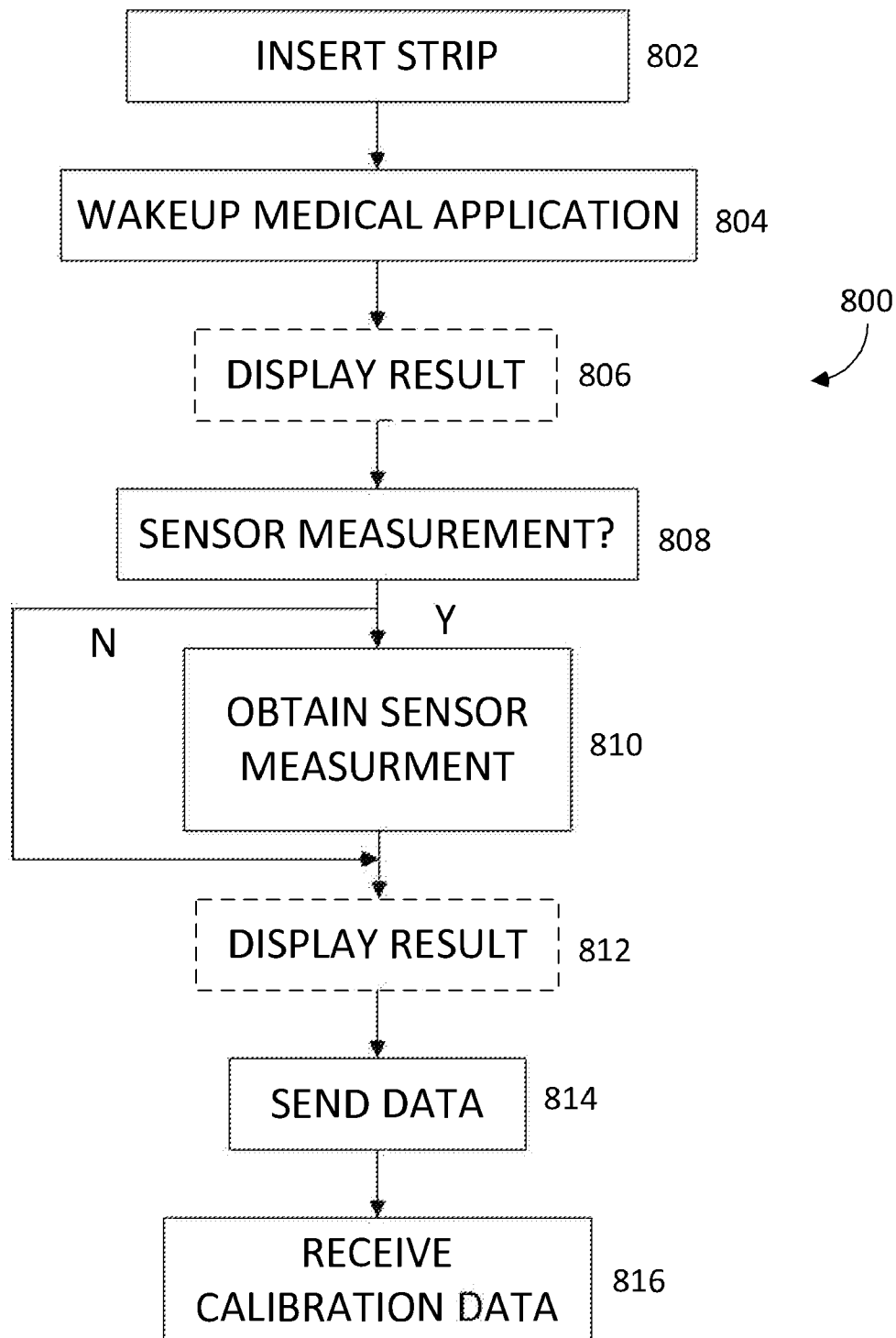
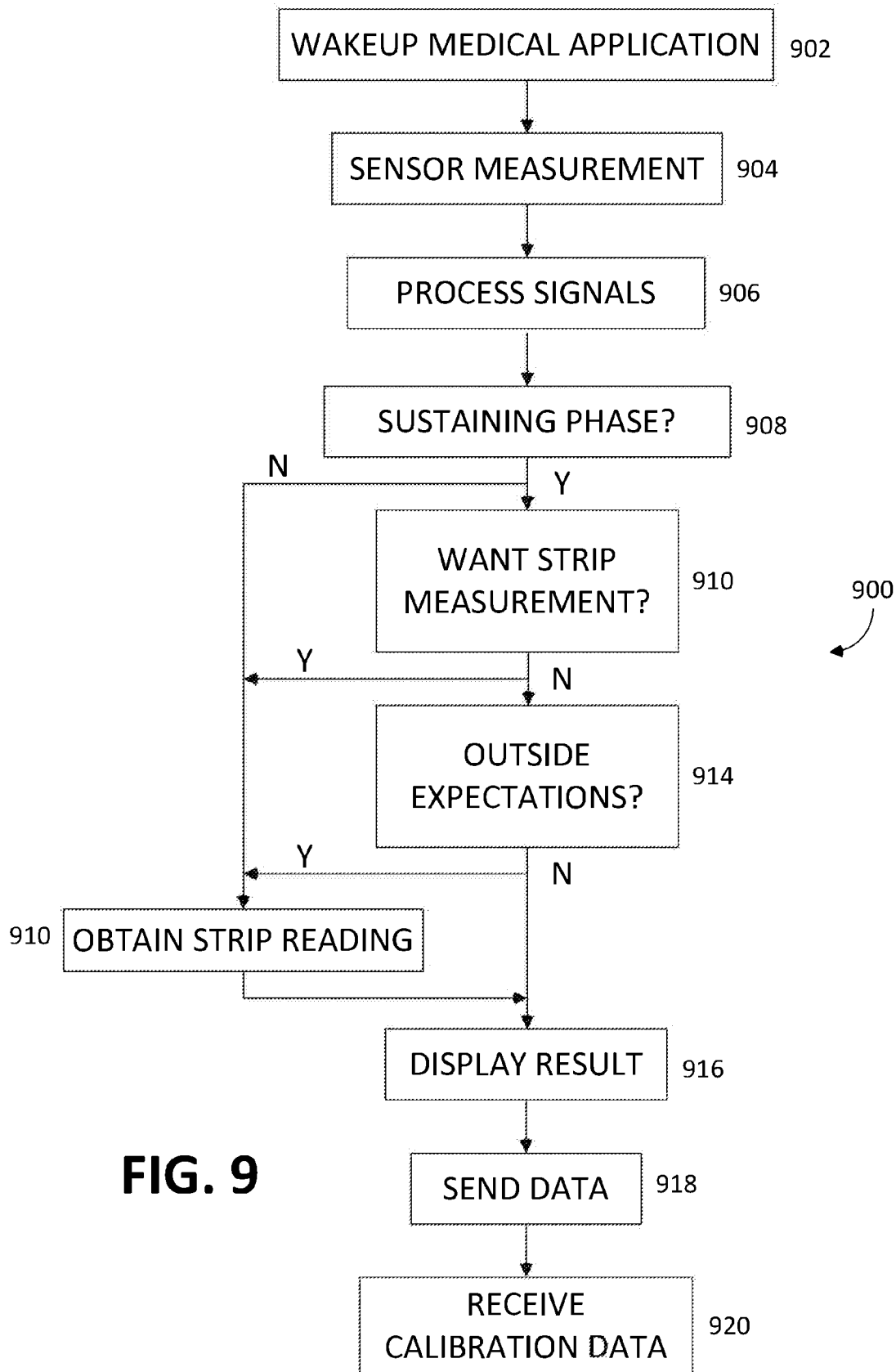


FIG. 8



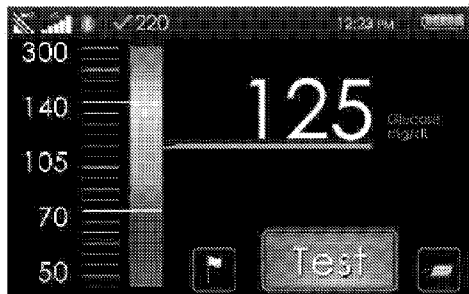


FIG. 10



FIG. 11

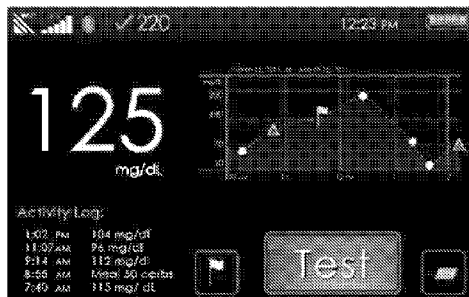


FIG. 12A

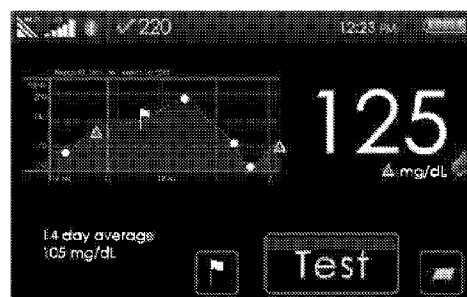


FIG. 12B

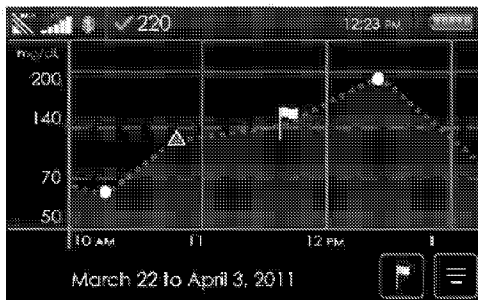


FIG. 13A

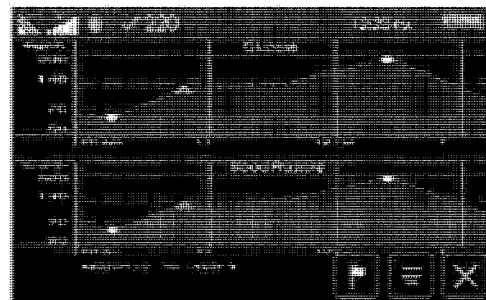


FIG. 13B

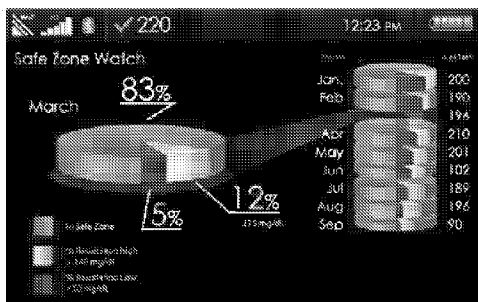


FIG. 13C

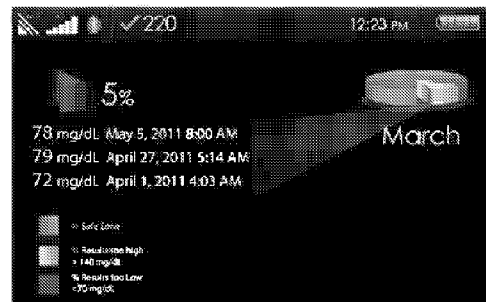


FIG. 13D



FIG. 14A



FIG. 14B



FIG. 15A

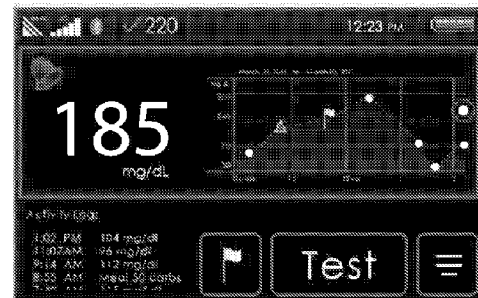


FIG. 15B

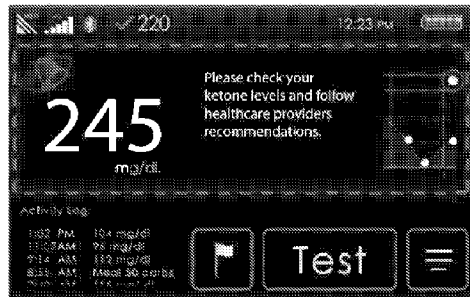


FIG. 15C

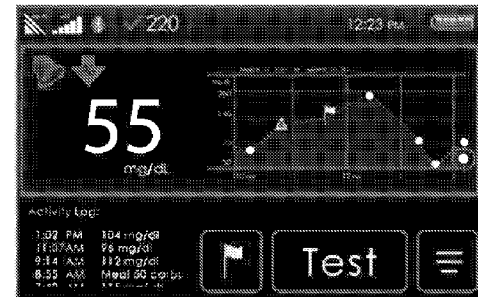


FIG. 15D



FIG. 16A

Glycemic Control	Adults with Diabetes	Prediabetes	Adults w/o Diabetes
Pre Meal Preprandial plasma glucose	130 - 70	100 - 125	100 - 70
Post Meal Approx. 2 hours after a meal Postprandial plasma glucose	< 180 mg/dL	22 mg/dL	< 140 mg/dL

FIG. 16B

advertisement	Account Name Account Balance
Buy new sensor	Current Standings:
Buy storage case	200 credits remain
Buy Insurance App	5 hrs. talk
Buy Pedometer App	200 SMS
Buy etc..	Buy test credits

FIG. 16C



FIG. 17



FIG. 18A

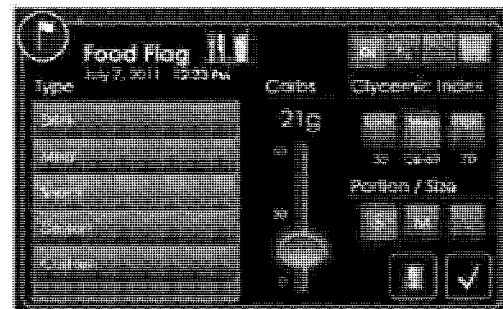


FIG. 18B

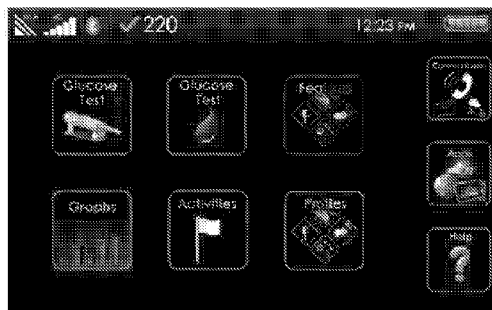


FIG. 19A



FIG. 19B

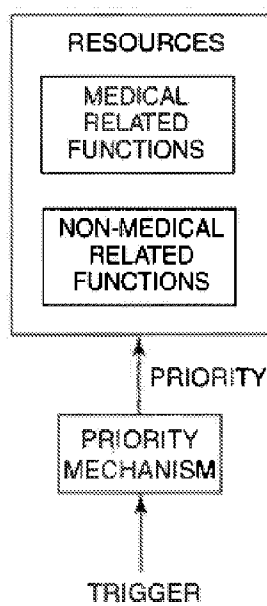


FIG. 20

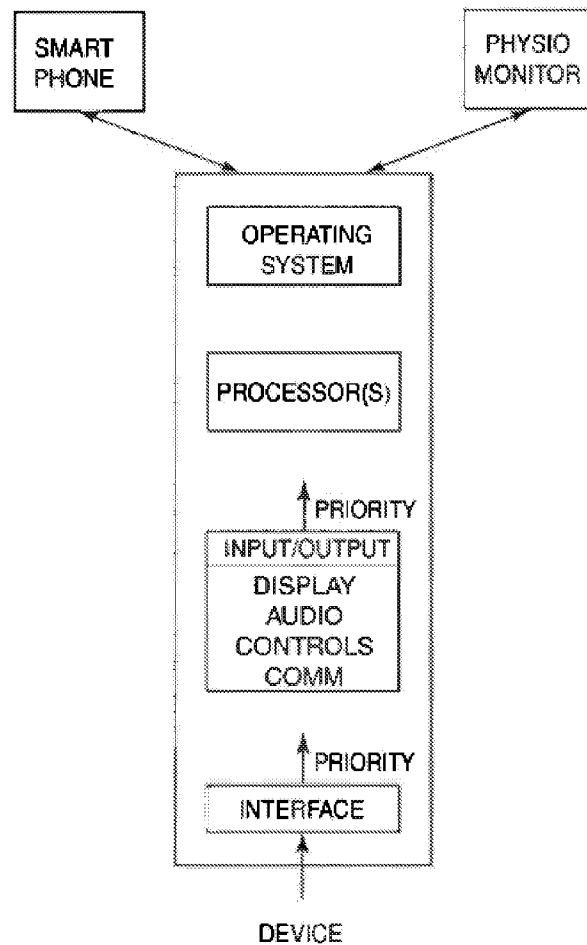


FIG. 21

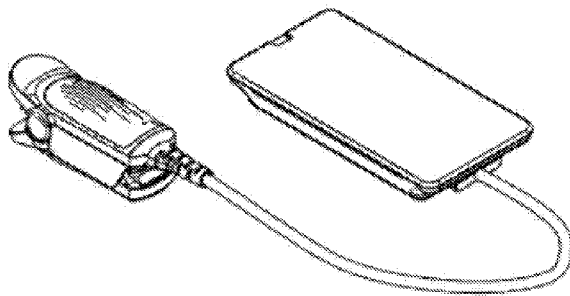


FIG. 22A

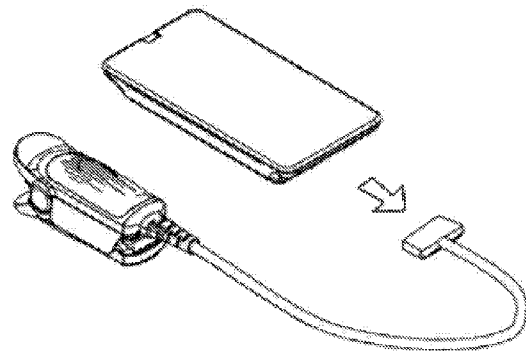


FIG. 22B

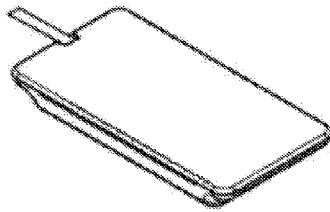


FIG. 22C

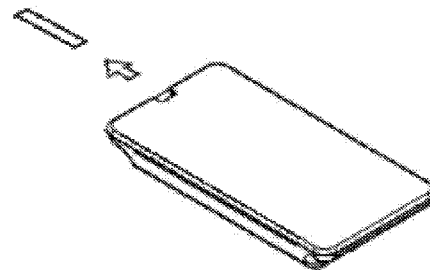


FIG. 22D

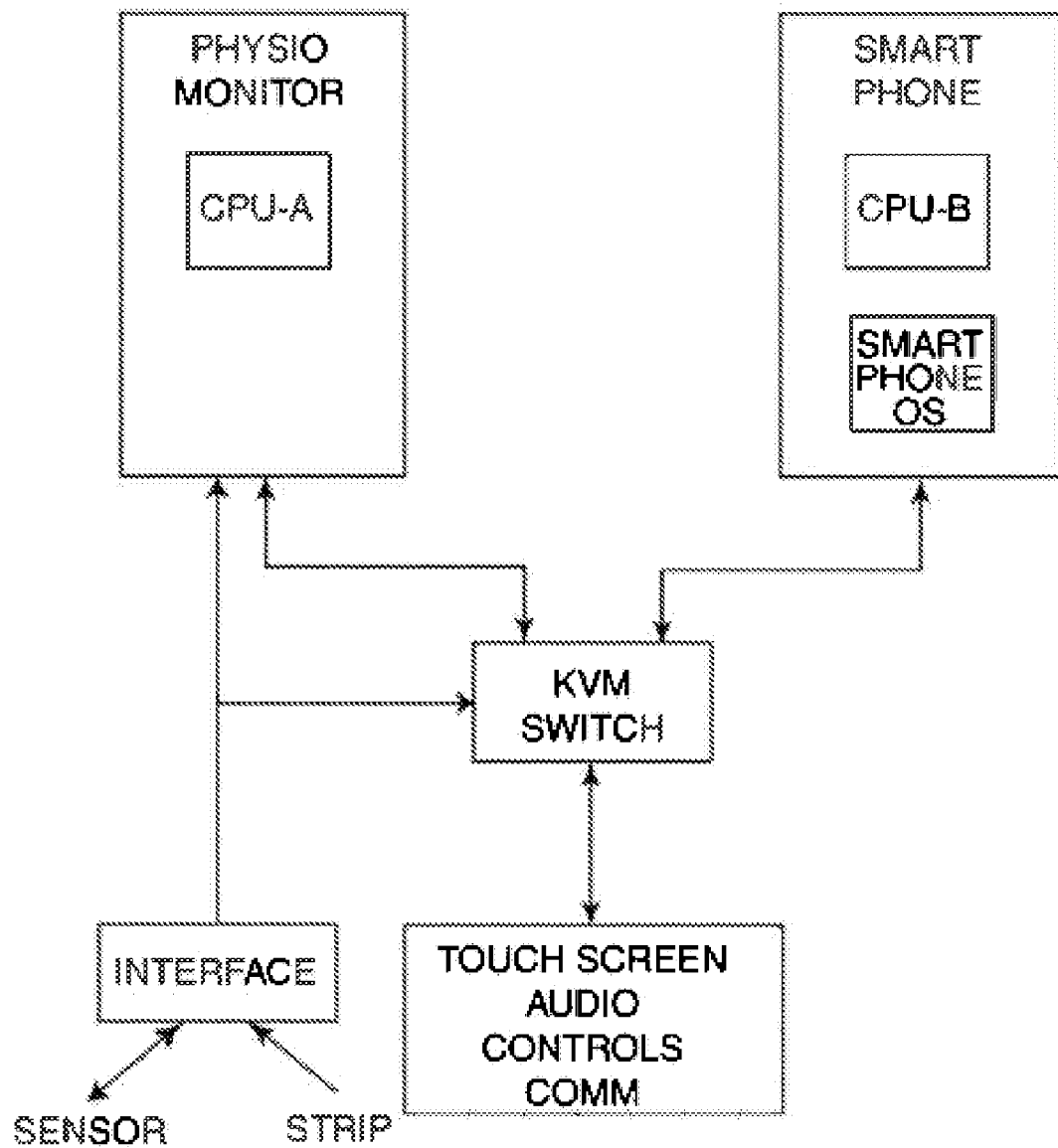


FIG. 23

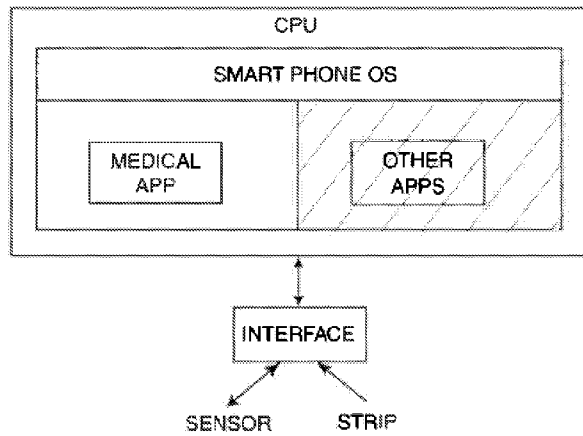


FIG. 24

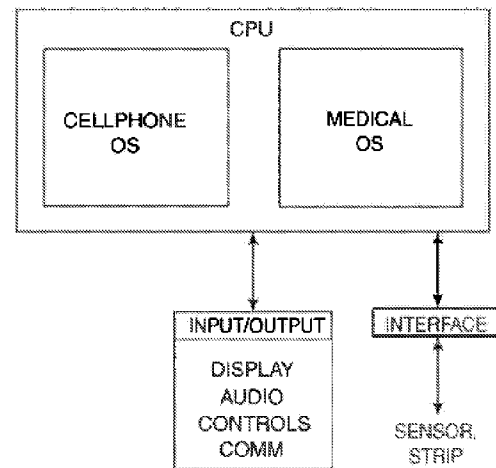


FIG. 25

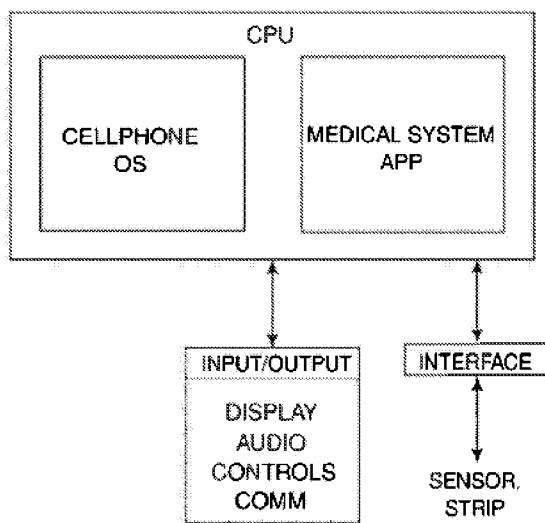


FIG. 26

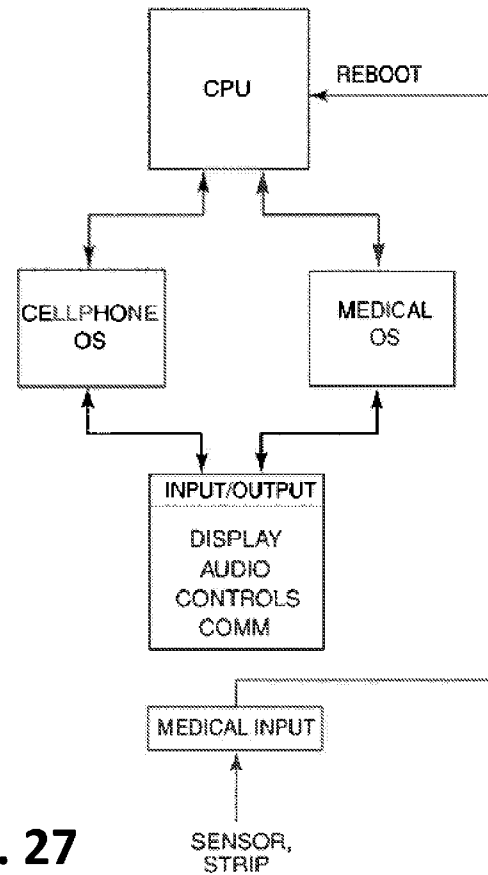


FIG. 27

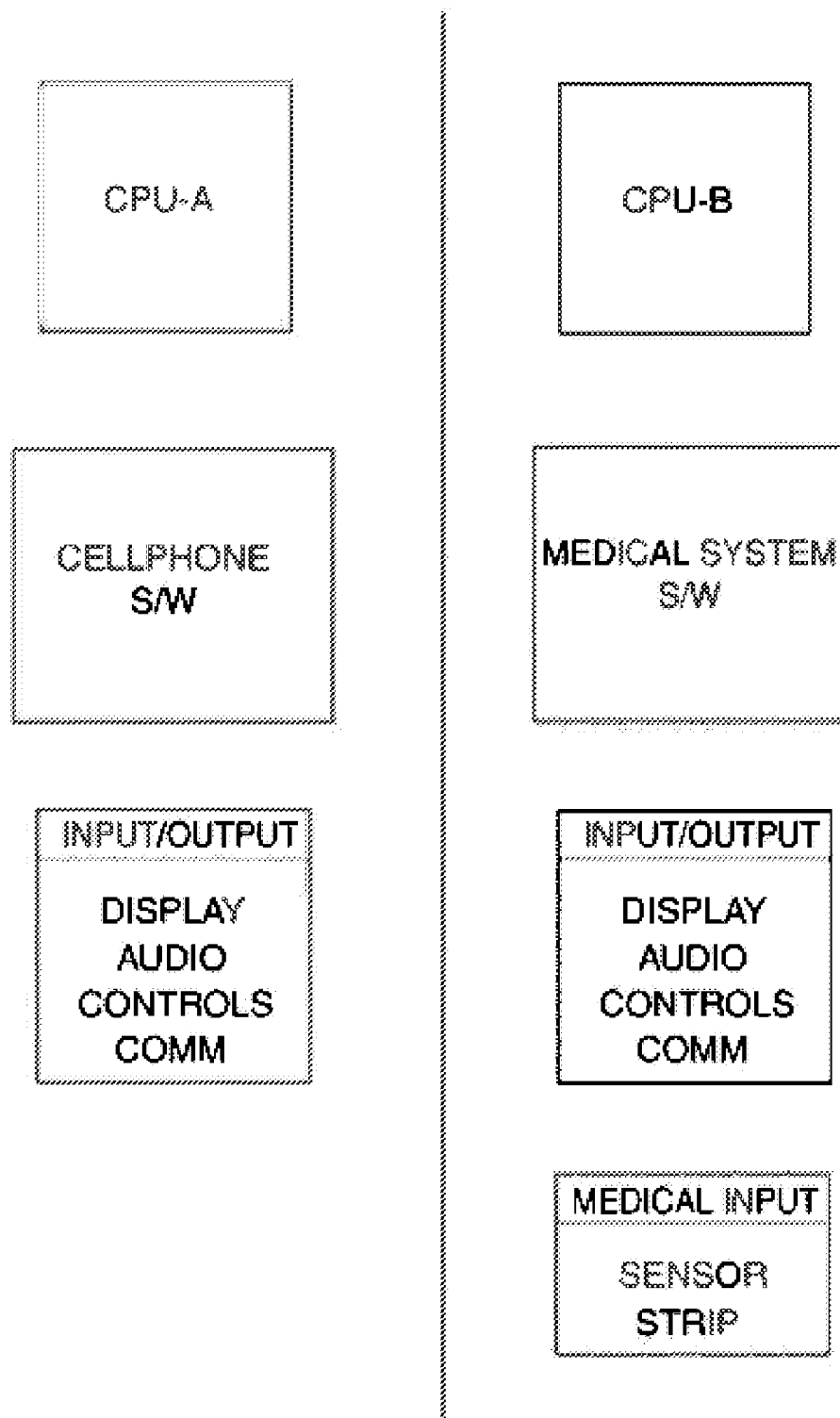


FIG. 28

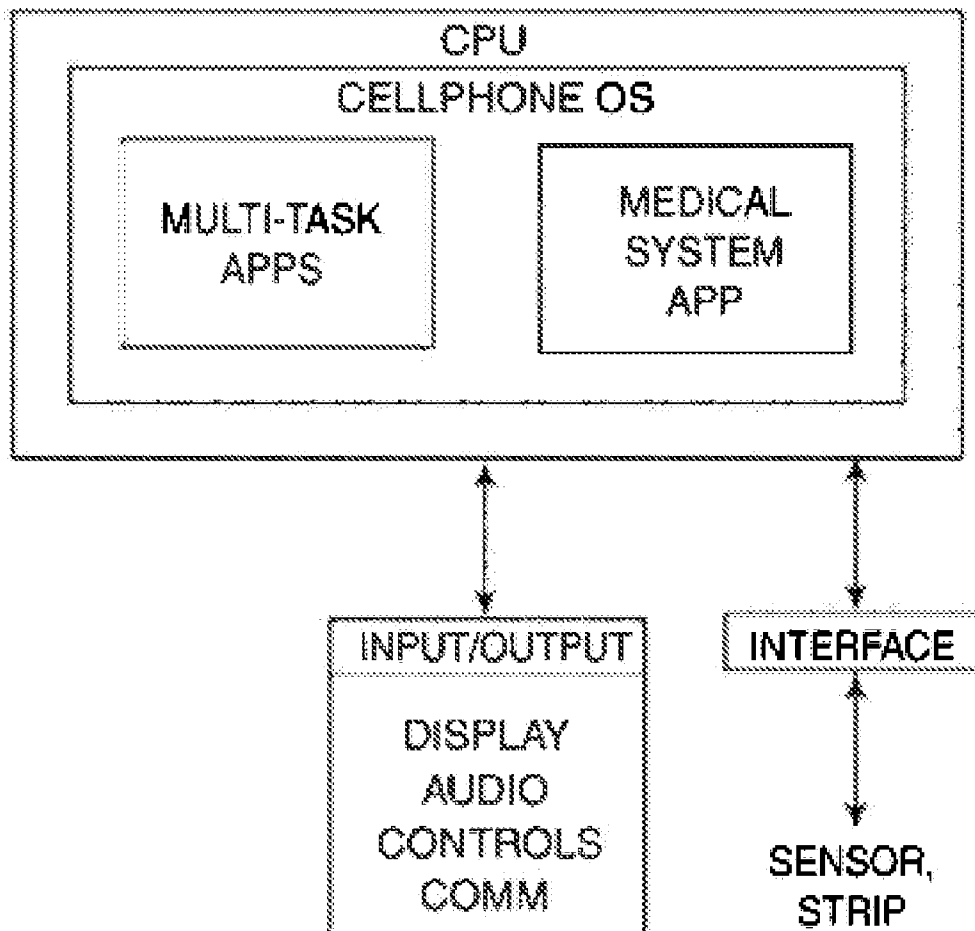


FIG. 29

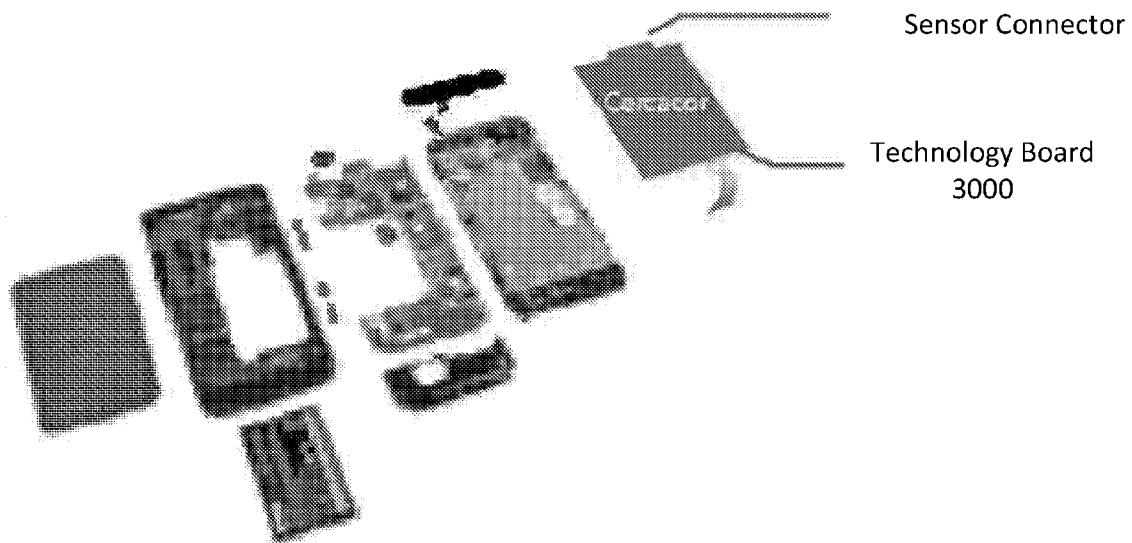


FIG. 30

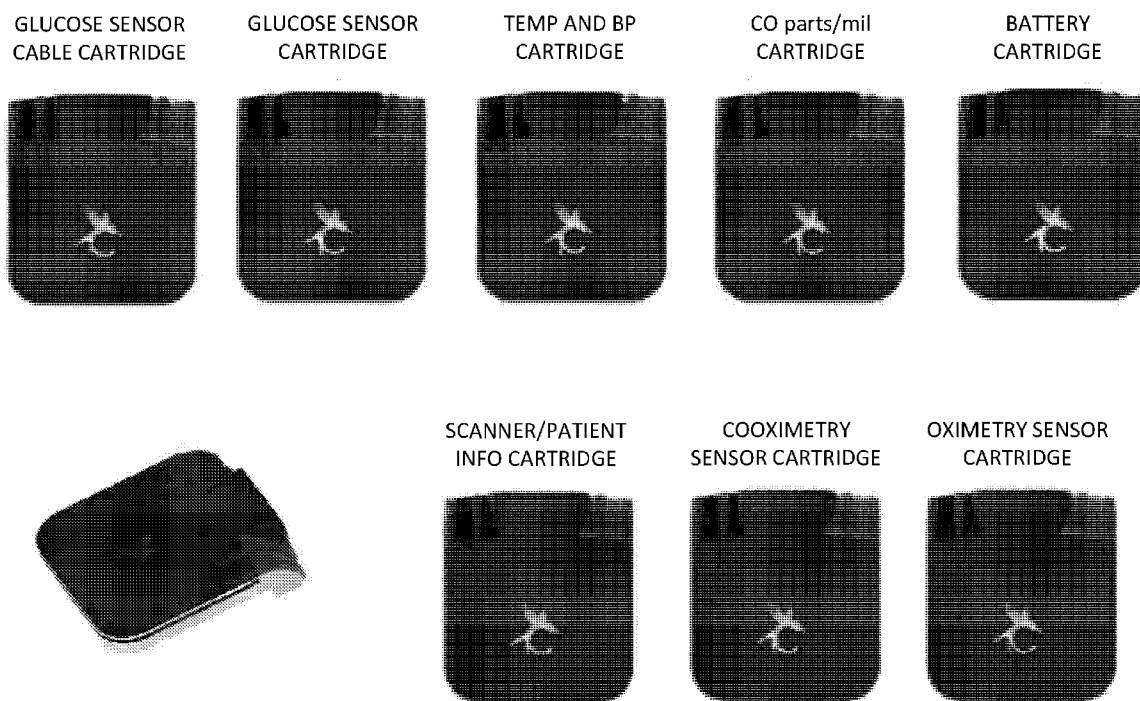


FIG. 31

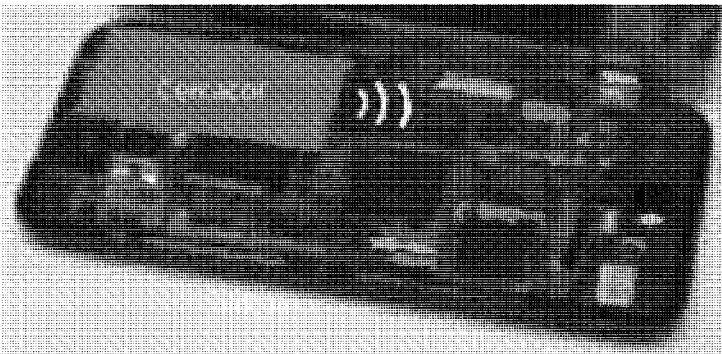


FIG. 32

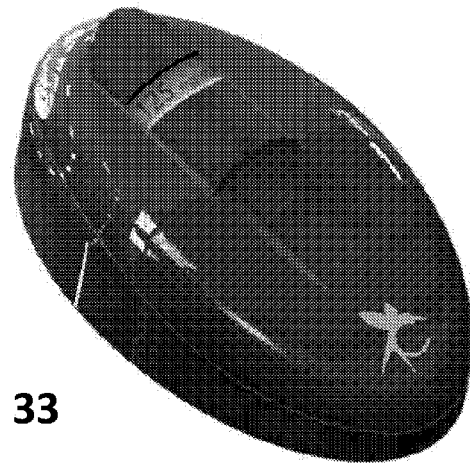
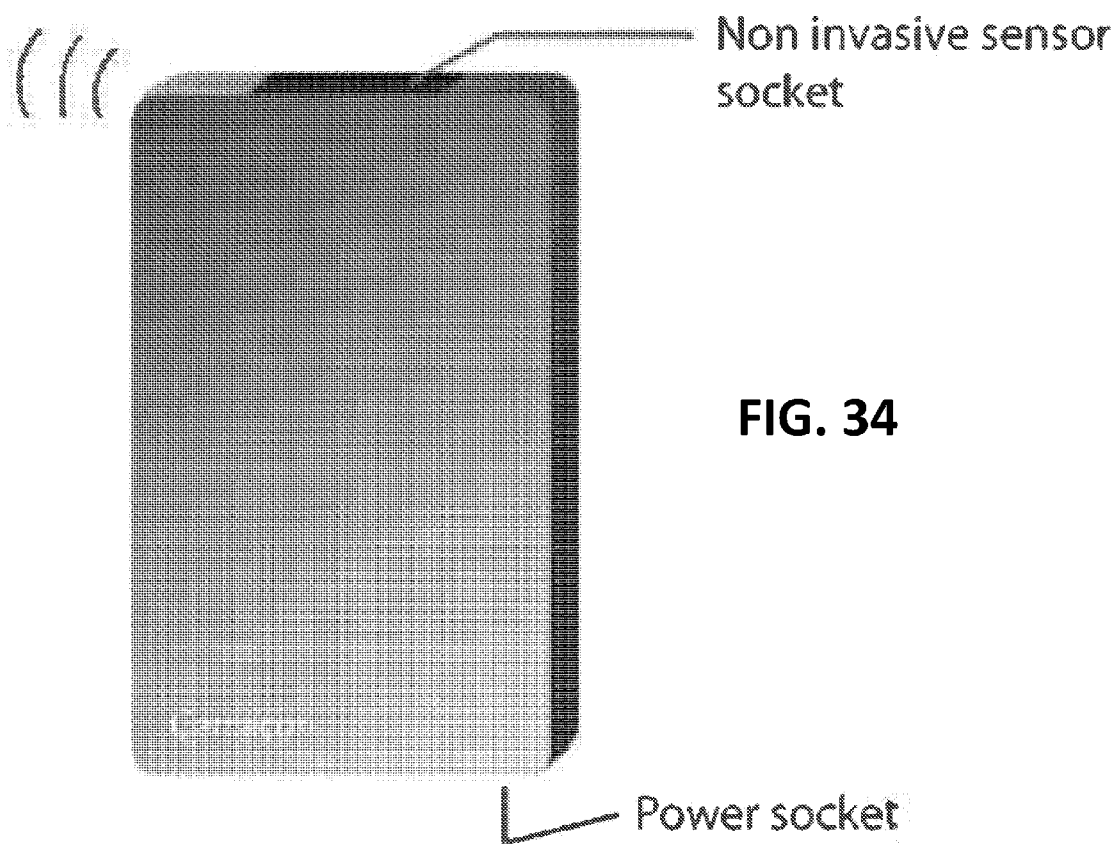


FIG. 33



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HANDHELD PROCESSING DEVICE INCLUDING MEDICAL APPLICATIONS FOR MINIMALLY AND NON INVASIVE GLUCOSE MEASUREMENTS

PRIORITY CLAIM AND REFERENCE TO RELATED APPLICATIONS

[0001] The present application claims a priority benefit under 35 U.S.C. §119(e) to U.S. Provisional Pat. App. Ser. No. 61/418,807, filed Dec. 1, 2010, titled “Smart phone For Managing Physiological Data” (Attorney Dock. No. MLHUM.039PR), and U.S. Provisional Pat. App. Ser. No. 61/422,284, filed Dec. 13, 2010, titled “Priority Mode Physiological Monitor” (Attorney Dock. Nos. MLABS-P41X and MLHUM.055PR). Each of the foregoing applications is incorporated by reference herein.

FIELD OF THE DISCLOSURE

[0002] The present application relates to the field of physiological monitoring devices. Specifically, the present application relates to the field of glucometers.

BACKGROUND OF THE DISCLOSURE

[0003] Medical device manufacturers are continually increasing the processing capabilities of patient monitors, specifically of patient monitors that process signals based on attenuation of light by patient tissue. In general, such patient monitoring systems include one or more optical sensors that irradiate tissue of a patient and one or more photodetectors that detect the radiation after attenuation thereof by the tissue. The sensor communicates the detected signal to a patient monitor, where the monitor often removes noise and preprocesses the signal. Advanced signal processors then perform time domain and/or frequency domain processing to determine measurements of blood constituents and other physiological parameters of the patient.

[0004] Manufacturers have advanced basic pulse oximeters that determine measurements for blood oxygen saturation (“SpO2”), pulse rate (“PR”) and pethysmographic information, to read-through-motion oximeters, to co-oximeters that determine measurements of many constituents of circulating blood. For example, Masimo Corporation of Irvine Calif. (“Masimo”) manufactures pulse oximetry systems including Masimo SET® low noise optical sensors and read through motion pulse oximetry monitors for measuring SpO2, PR, perfusion index (“PI”) and others. Masimo sensors include any of LNOP®, LNCS®, SofTouch™ and Blue™ adhesive or reusable sensors. Masimo oximetry monitors include any of Rad-8®, Rad-5®, Rad®-5v or SatShare® monitors.

[0005] Many innovations improving the measurement of blood constituents are described in at least U.S. Pat. Nos. 6,770,028; 6,658,276; 6,157,850; 6,002,952; 5,769,785 and 5,758,644, which are assigned to Masimo and are incorporated by reference herein. Corresponding low noise optical sensors are disclosed in at least U.S. Pat. Nos. 6,985,764; 6,088,607; 5,782,757 and 5,638,818, assigned to Masimo and incorporated by reference herein.

[0006] Masimo also manufactures more advanced co-oximeters including Masimo Rainbow® SET, which provides measurements in addition to SpO2, such as total hemoglobin (SpHb™), oxygen content (SpCO™), methemoglobin (SpMet®), carboxyhemoglobin (SpCO®) and PVI®. Advanced blood parameter sensors include Masimo Rain-

bow® adhesive, ReSposable™ and reusable sensors. Masimo’s advanced blood parameter monitors include Masimo Radical-7™, Rad-87™, and Rad57™ monitors as well as Pronto and Pronto-7 spot check monitors.

[0007] Innovations relating to these more advanced blood parameter measurement systems are described in at least U.S. Pat. Nos. 7,647,083; 7,729,733; U.S. Pat. Pub. Nos. 2006/0211925; and 2006/0238358, assigned to Cercacor Laboratories of Irvine, Calif. (“Cercacor”) and incorporated by reference herein.

[0008] Such advanced pulse oximeters, low noise sensors and advanced blood parameter systems have gained rapid acceptance in a wide variety of medical applications, including surgical wards, intensive care and neonatal units, general wards, home care, physical training, and virtually all types of monitoring scenarios.

SUMMARY OF THE DISCLOSURE

[0009] The present disclosure includes a handheld processing device including medical applications for minimally and noninvasive glucose measurements. In an embodiment, the device includes a minimally invasive glucose biosensor (“strip reader”). Manufacturers have developed strip readers in various embodiments for decades primarily for the measurement of glucose. Such strip readers often employ disposable strips that include an enzyme electrode and mediator compound, where the mediator compound moves electrons between the enzyme and the electrode to result in a measurable electrical current at the electrode when glucose is present. The strip reader measures this current when the disposable strip is inserted and then determines glucose values corresponding to the received current. Diabetics, for example, often rely on strip readers to provide minimally invasive measurements of their glucose levels. In short, a user often pricks a finger and deposits one or more droplets of blood on a test strip. The user then inserts the blood carrying strip into a strip reader, which in turn uses the measurable electrical signal to determine glucose measurements for the user.

[0010] In an embodiment, the device also includes a non-invasive glucose measurement solution. For example, the device communicates with a noninvasive optical sensor to receive signals responsive to the attenuation of various wavelengths of light by a user’s tissue. The device processes these signals to determine current glucose measurements for the user.

[0011] As is widely understood by one of ordinary skill in the glucose measurement arts, noninvasive determination of glucose through processing absorption signals is complicated and often difficult to accurately perform over large patient populations. In an embodiment of the present disclosure, patient specific calibration of the device occurs through information exchanges between the device, with its the minimally invasive and noninvasive measurements, and a centralized computing system. For example, the device communicates with one or more remote computing centers to upload patient measurements and download, for example, patient specific calibrations. Through the interaction of the centralized computing system and many processing devices as disclosed herein, the manufacturer collects vast amounts of anonymous physiological data associating minimally invasive measurements and noninvasive measurements. These associations can then produce reliable calibration data specific to a user and across large user populations. For example, in certain

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embodiments, uploads of thousands to hundreds of thousands of measurements per week create data resources unobtainable through traditional clinical testing environments.

[0012] Additional embodiments of the present disclosure include the processing device including medical related functions and non-medical related functions that may share common resources. Advantageously, the processing device includes a priority mechanism so as to prevent the medical related functions from competing with the non-medical related functions for the common resources during critical time periods. These critical time periods may be indicated by triggering events. In particular, a triggering event indicates to the system that the medical related functions have resource priority. This priority may be, for example, exclusive access to and use of displays, alarms, controls, communications and processing power so as to make time critical patient health and risk assessments and output those assessments in a timely manner to a healthcare provider. In an embodiment, the physiological monitor is integrated with a smart phone so as to advantageously allow flexible communications between the physiological monitor and a broad range of external information sources and information receivers. These communications occur over any of a wide variety of communication links, both wired and wireless. Wireless communications may include, but are not limited to, GPS, cellular networks, Wi-Fi and Bluetooth to name a few, so as to connect to the Internet, telephone systems and other wide area networks. Wired communications may include, but are not limited to, USB. A broad range of third-party applications are available for the smart phone, also providing increased functionality to the physiological monitor.

[0013] In additional embodiments, the processing device may include the alteration of smart phone processing systems to manage physiological data. For example, in some embodiments, a processing board or card may be included within an existing smart phone technology. The board or card may include one or more signal processors and associated memory, I/O, and the like to provide measurement or other physiological data to applications executing on traditional smart phone processing environments. In an embodiment, the communication may be wired or wireless and the board or card may be internal or external. In some cases, the board may be a clip-on cartridge or other smart phone extension that electronically and/or physically mates with the housing and processing of the smart phone.

[0014] In an embodiment, a monitoring board may be physically integrated and attach to a connected sensor. In another embodiment, the monitoring board may mechanically and/or electrically mate with the smart phone. In this embodiment, the sensor may include the monitoring board, which then communicates with a smart phone, or portions of the monitoring board may be shared between an external sensor and the smart phone. In a standalone embodiment, the monitoring board and the sensor may be an integrated unit or a unit with an attached sensor, where the unit communicates with smart phone or other digital processing devices.

[0015] For purposes of summarizing the invention, certain aspects, advantages and novel features of the invention have been described herein. Of course, it is to be understood that not necessarily all such aspects, advantages or features will be embodied in any particular embodiment of the invention.

[0016] For purposes of summarizing the invention, certain aspects, advantages and novel features of the invention have been described herein. Of course, it is to be understood that

not necessarily all such aspects, advantages or features will be embodied in any particular embodiment of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

[0017] The following drawings and the associated descriptions are provided to illustrate embodiments of the present disclosure and do not limit the scope of the claims.

[0018] FIG. 1 illustrates a simplified perspective view of a processing system according to an embodiment of present disclosure, including a processing device, a noninvasive sensor, a cable providing communication between the device and the sensor, and a disposable strip.

[0019] FIG. 2 illustrates a simplified perspective view of the processing device of FIG. 1, according to an embodiment of present disclosure.

[0020] FIGS. 3A-3F illustrate simplified top, front, rear, left, right, and back views of the processing device of FIG. 1, according to an embodiment of present disclosure.

[0021] FIGS. 4A-4B illustrate simplified exploded views of the processing device of FIG. 1, according to an embodiment of present disclosure.

[0022] FIG. 5 illustrates a simplified hardware/software block diagram of the processing system of FIG. 1, according to an embodiment of present disclosure.

[0023] FIG. 6 illustrates a simplified data flow diagram between applications of the processing device of FIG. 1 and remote computing servers, according to an embodiment of present disclosure.

[0024] FIG. 7 illustrates a simplified measurement process according to an embodiment of the present disclosure.

[0025] FIG. 8 illustrates a simplified minimally invasive strip measurement process according to an embodiment of the present disclosure.

[0026] FIG. 9 illustrates a simplified noninvasive sensor measurement process according to an embodiment of the present disclosure.

[0027] FIGS. 10-19 illustrate exemplary user interfaces of the processing device of FIG. 1, according to various embodiments of the present disclosure. Specifically, FIG. 10 illustrates an exemplary test result interface, FIG. 11 illustrates an exemplary bar graph interface, FIGS. 12A-12B illustrate exemplary result and trend interfaces, FIGS. 13A-13D illustrate exemplary trend interfaces, FIGS. 14A-14B illustrate exemplary calibration protocol interfaces, FIGS. 15A-15D illustrate exemplary alarm interfaces, FIGS. 16A-16C illustrate exemplary instructive interfaces, FIG. 17 illustrates an exemplary applications interface, FIGS. 18A-18B illustrate exemplary events interfaces including a food flag interface, and FIGS. 19A-19B illustrate exemplary priority interfaces.

[0028] FIG. 20 illustrates a simplified block diagram of a priority mode processing device according to an embodiment of the present disclosure.

[0029] FIG. 21 illustrates a simplified block diagram of a priority mode processing device according to an embodiment of the present disclosure.

[0030] FIGS. 22A-22D illustrate priority mode glucometers according to embodiments of the present disclosure showing connected and disconnected sensors and inserted and removed test strips, respectively.

[0031] FIG. 23 illustrates a simplified block diagram of priority mode processing device utilizing a KVM switch for priority control according to an embodiment of the present disclosure.

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[0032] FIG. 24 illustrates a simplified block diagram of priority mode processing device utilizing an activated medical app for priority control according to an embodiment of the present disclosure.

[0033] FIG. 25 illustrates a simplified block diagram of priority mode processing device utilizing separate virtual machines for priority control according to an embodiment of the present disclosure.

[0034] FIG. 26 illustrates a simplified block diagram of priority mode processing device utilizing a cell phone operating system that is suspended in favor of a medical system application when a sensor or strip is detected according to an embodiment of the present disclosure.

[0035] FIG. 27 illustrates a simplified block diagram of priority mode processing device having dual-booted operating systems according to an embodiment of the present disclosure.

[0036] FIG. 28 illustrates a simplified block diagram of priority mode processing device having double-sided device functionality according to an embodiment of the present disclosure.

[0037] FIG. 29 illustrates a simplified block diagram of priority mode processing device running a single medical application in lieu of a multi-task normal operating mode according to an embodiment of the present disclosure.

[0038] FIG. 30 illustrates a simplified exploded view of an expanded smart phone including internally integrated medical processing capability according to an embodiment of the disclosure.

[0039] FIG. 31 illustrates various exemplary connectable cartridges for an expanded smart phone to provide medical processing capabilities, according to an embodiment of the disclosure.

[0040] FIGS. 32-34 illustrate medical processing cartridges as separate units communicating to create an expanded smart phone according to embodiments of the disclosure.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0041] The present disclosure includes a handheld processing device including medical applications for minimally and noninvasive glucose measurements. In an embodiment, the device creates a patient specific calibration using a measurement protocol of minimally invasive measurements and non-invasive measurements, eventually creating a patient specific calibrated noninvasive glucometer. Additionally, embodiments of the present disclosure provide for the processing device to execute medical applications and non-medical applications. In an embodiment the medical applications may advantageously relate to the foregoing patient specific non-invasive glucometer. Such applications may advantageously include measurement applications, tracking applications including diet applications to track caloric intake and/or caloric usages, calendaring, and other glucose management applications. In other embodiments, other medical applications may monitor respiration, blood pressure, other blood parameters, combinations of parameters, wellness measurements or the like. The nonmedical applications may include communication protocols, connectivity protocols, smart phone and cellphone capabilities, entertainment applications, productivity applications, or virtually any application available on today's existing sophisticated smart phones.

[0042] In other embodiment's, the processing device generates patient specific calibrations through information exchanges between the device and a centralized computing system. For example, the device may upload measurement information to one or more remote computing data centers over wireless, mobile, Wi-Fi, wired, or other networks and download patient specific or other updated calibrations. Advantageously, through the upload of measurement data, the manufacturer may collect anonymous clinical data that can be used to create ever more accurate noninvasive measurements.

[0043] According to further embodiments, the processing device includes medical and nonmedical applications that may share common resources. Advantageously, the processing device includes a priority mechanism so as to prevent the medical related functions from competing with the non-medical related functions for the common resources during critical or otherwise medically relevant time periods.

[0044] In still further embodiments of the present disclosure, such processing devices as disclosed herein may be incorporated into existing smart phone processing platforms.

[0045] To facilitate a complete understanding of the invention, the remainder of the detailed description describes the invention with reference to the drawings, wherein like reference numbers are referenced with like numerals throughout.

[0046] FIG. 1 illustrates a simplified perspective view of a processing system 100 according to an embodiment of present disclosure, including a processing device 102, a non-invasive sensor 104, an associated cable 106 providing communication between the device 102 and the sensor 104, and a disposable glucose strip 108. The processing device 100 comprises a handheld housing including an integrated touch screen 110, one or more input keys 112, and an integrated camera 113 preferably capable of photo and/or video capture. In an embodiment, the screen 110 rotates as the device 102 is held in differing orientations; however, the preferred orientation is for use is the landscape orientation as illustrated in FIG. 2.

[0047] FIG. 1 also illustrates additional features of the device 102. For example, the device 102 includes along a side thereof an integrated strip reader, including a strip input cavity 114, and a power button 116. Along another side, the device 102 includes a noninvasive sensor cable input port 120 (FIG. 3E) and volume controls 122 (FIG. 3E). Along yet another side, the device 102 includes a headphone jack 124, a micro SD card reader input cavity 126, a micro HDMI connector 128, a Micro USB connector 130 configured for, for example, data transfer and battery charging, and an optional audio transducer, such as, for example, a speaker 132. Along a back side thereof, in an embodiment, the processing device 102 includes a camera 134 (FIG. 3F) and LED flash 136 (FIG. 3F).

[0048] As disclosed, the device 102 communicates with a noninvasive optical sensor 104, such as, for example, a clothespin style reusable optical sensor, in some mechanical respects similar to those employed in standard pulse oximetry. The sensor 104 may also include advanced features, such as those disclosed in U.S. Pat. No. 6,580,086, and U.S. Pat. Pub. No. 2010-0026995, on Feb. 4, 2010, titled "Multi-stream Sensor For Noninvasive Measurement of Blood Constituents," each of which is incorporated by reference herein. Specifically, the sensor 104 includes a plurality of emitters emitting light of a variety of wavelengths to form a light source. A plurality of detectors detect the light after attenua-

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tion by a digit of the patient. A plurality of temperature sensors and one or more memory devices may also be incorporated into the sensor 104. These devices communicate their information to the device 102 through the cable 106.

[0049] In general, the user interacts with the processing device 102 to obtain glucose measurements. The user may input the disposable strip 108 with a blood sample and the device 102 will, if not already, electronically wake up a medical application and display glucose measurements obtained from the strip reader. The user may also apply the sensor 104 to a digit and upon activating a “test” input, the device 102 may process the detector signals and display glucose measurements derived from the received signals.

[0050] Although disclosed with respect to the embodiment shown in FIG. 1, an artisan will recognize from the disclosure herein alternative or additional functionality, user interaction mechanisms, and the like. For example, the device housing may be shaped to ergonomically fit a user’s hand, may include more or less input mechanisms including, for example, a connectable or slideout keyboard, a pointing device, speech recognition applications, or the like. Moreover, the sensor 104 may wirelessly communicate with the device 102. The device 102 may communicate with an external strip reader or other medical sensors or devices.

[0051] FIGS. 3A-3F illustrate simplified top, front, rear, left, right, and back views of the processing device 102 of FIG. 1, according to an embodiment of present disclosure.

[0052] FIGS. 4A-4B illustrate simplified exploded views of the processing device 102 of FIG. 1, according to an embodiment of present disclosure. As shown, the device 102 includes the touch screen 110 housed in an upper housing 400, a main frame 402, a main board 404, a battery 406 and a rear housing or casing 408. In an embodiment, the touch screen 110 comprises a 5.6" LED backlit LCD with 1280x800 pixel resolution with 262,144 colors and a viewing angle of 179 degrees, although an artisan will recognize from the disclosure herein a wide variety of possible display devices.

[0053] FIG. 5 illustrates a simplified hardware block diagram 500 of the processing system 100 of FIG. 1, according to an embodiment of present disclosure. As shown in FIG. 5, the processing device 102 includes a plurality of processors, including a front end processor 502 configured to execute a number of processes, including medical processes and signal processing processes, a coprocessing DSP 504 configured to execute a number of calculators and assist the front end 502 in intensive calculation processes, and an applications processor 506, configured to execute a medical applications and more traditional smart phone applications, including, for example, cell phone, internet, entertainment, and productivity applications. In an embodiment, the front end 502 comprises an OMAP style processing system available from Texas Instruments, generally comprising an ARM9 processor and one or more digital signal processors or specialized co-processors. In an embodiment, the front end 502 may comprise an OMAP L138 processor system. In an embodiment, the coprocessor 504 comprises a Snowbird style digital signal coprocessor from Analog Devices. In an embodiment, the applications processor 506 comprises a Linux processor from Samsung including a Cortex-A9 ARM processor.

[0054] Although disclosed with reference to specific processing technologies, an artisan will recognize from the disclosure herein that the processor could comprises a single processing device, more or less than three (3) processing

devices, a wide variety of hardware and/or software solutions, other processing devices, or the like.

[0055] The front end 502 communicates with the sensor 104 components to accomplish the noninvasive measurements of the present disclosure. For example, the front end 502 communicates with one or more light sources 510 to irradiate a digit 512 of a wearer of the sensor 104. A plurality of photodetectors 514 receive the irradiated light after attenuation by the tissue of the digit 512. In an embodiment, the detectors 514 comprises four (4) detectors logarithmically spaced apart along an axis parallel to a long axis of the digit 512, the detectors 514 optionally mounted on an actuator 516. In an embodiment, the actuator 516 moves the detectors in a predefined motion to create an active pulse technology, similar to that disclosed in U.S. Pat. No. 5,638,816, titled “Active Pulse Blood Constituent Monitoring,” or in U.S. Pat. Prov. App. Ser. No. 61/486,689 filed on May 16, 2011, titled “Personal Health Device,” each of which is incorporated by reference herein. The detectors 514 output their respective channels of data, or signals to the front end 502 for processing. In addition to the light source 510 and the detectors 514, the front end 502 may advantageously communicate with a plurality of temperature sensors 518, and one or more memories 520. In an embodiment, the front end 502 communicates with a temperature sensor 518 configured to supply an indication of the temperatures of the emitting LEDs of the light source 510, a temperature sensor 518 configured to supply an indication of the temperature of the tissue being monitored, and a temperature sensor 518 configured to supply and indication of the temperature of the detectors 514.

[0056] The front end processor 502 also communicates extensively with the coprocessor 504 over, for example, a dedicated high speed connection. In an embodiment, the medical application algorithms and mathematics that generate noninvasive measurements may be regarded as highly sensitive information. Thus, the communication between the processors 502 and 504 may advantageously be encrypted to ensure their sensitivity is appropriately guarded.

[0057] The front end processor 502 additionally communicates with the applications processor 506. In an embodiment, determined measurement values are forwarded to the applications processor 506, where, for example, medical applications use the data to present information to the user on the display 110. The applications processor 506 also communicates with the strip reader 520. In an embodiment, the strip reader 520 comprises a commercially available OEM strip reader from, for example, Nova Medical. In an embodiment, the strip reader includes a current detector, or reader 522 and a controller 524 for determining from an inserted strip 108, minimally invasive glucose measurements. The reader 520 forwards calculated measurements to the applications processor 506, where, for example, medical applications use the data to present information to the user on the display 110.

[0058] As disclosed in the foregoing, the applications processor 506 executes a wide variety of medical applications and smart phone or other applications, any of which may access wireless communication functionality, including Wi-Fi, 3 and/or 4 G or higher connectivity, Bluetooth, Ant, near field communication (“NFC”), cellular, or other wireless connectivity, SD card functionality, HDMI functionality, image and video data, and user input.

[0059] Although disclosed with reference to the specific embodiment of FIG. 5, an artisan will recognize from the disclosure herein other hardware and/or software configura-

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tions for accomplishing the desired functionality, including, for example, custom semiconductors, controllers, processors, or the like for performing individual or sets of functions.

[0060] FIG. 6 illustrates a simplified data flow diagram between applications of the processing device 102 of FIG. 1 and remote computing servers, according to an embodiment of present disclosure. As shown in FIG. 6, a health monitor 602 including, for example, the glucometer as disclosed above, communicates data with a number of other processing centers, including a number of applications 604 and at least one remote data processing center 606. As shown in FIG. 6, the health monitor 602 may communicate with one or more of the following sensors, devices, or technologies: ECG and/or EEG sensors or devices, respiration sensors or devices, including acoustic sensors such as those commercially available from Masimo, sleep apnea sensors or monitors, invasive technologies such as the above discussed strip reader or other invasive technologies, blood pressure sensors or devices, temperature sensing technologies, drug testing sensors or devices, depth of consciousness sensors or devices, and other patient monitoring devices. As shown in FIG. 6, this interaction with the monitor 602 advantageously allows the monitor to use the information in its medical calculations, as well provide that information further to various applications 604 and the remote processing center 606.

[0061] The applications 604 may include a wide variety of applications including, for example, the health applications disclosed herein, or similar applications, phone, business, entertainment including video, music, pictures, and the like, productivity, social, games, utility applications and the like, many of which can be associated with today's smart phone technologies. In an embodiment, the applications may include some combination or all of the applications disclosed in U.S. Pat. App. Pub. No. 2011-0082711, filed on Apr. 7, 2011, titled, "Personal Digital Assistant or Organizer for Monitoring Glucose Levels," incorporated by reference herein.

[0062] The remote data processing center 606 communicates with the health monitor 602 and the applications 604 to store and process vast amounts of data, including for example, minimally and noninvasive glucose measurements for patient specific and population calibration processing, electronic medical records ("EMR") and electronic health records ("EHR"), or the like. In an embodiment, the remote data processing center 606 may also perform device management functions, including, for example, maintenance of software and firmware executing on the processing device 102, and measurement credit processing, such as the measurement credit processing disclosed in U.S. Pat. App. Pub. No. 2011-0172498, filed Jul. 14, 2011, titled "Spot Check Monitor Credit System," incorporated by reference herein disclosing, in general, embodiments for managing spot check pricing for medical instruments.

[0063] As will be understood by an artisan from the disclosure herein, the data processing center 606 may comprise one or many physical and/or logical locations, servers, systems, or the like, accessible by any of a large number of connectivity options. It may be geographically distributed, may have mirrored or backup sites, may be one or many processing device or the like.

[0064] Communication between the device 102 and the remote data processing center 606 advantageously benefits all parties. For example, the user by sharing their measurement data in a confidential and/or anonymous manner pro-

vides valuable data to, for example, the manufacturer. The amount of this data could be staggering when compared with the amount of data traditionally gathered during clinical trials. Supplementing actual clinical trial information with valuable uploaded information provides a cost effective and time-wise practical solution to very costly clinical trial studies. In return, the user receives from the remote processing center patient specific calibration data ensuring the most accurate association of absorption-derived data and output measurement data. For example, oximeters and cooximeters use clinical data to map noninvasive measurement results to clinically-determined output measurements. This mapping is often referred to as "calibration." With the present disclosure, the clinical data is vastly supplemented with user data creating much more accurate calibrations, and specifically, user-specific calibrations. These calibrations are downloaded to the monitor 602.

[0065] For example, because of many challenges associated with the accurate noninvasive optical absorption-based glucose measurements, variability in calibrations between subjects can be high, in some cases too high for global calibrations to accurately support large user populations. Thus, in an embodiment of the present disclosure, the processing device 102 improves its calibration for a specific user through communication with the data processing center 606. In an embodiment, qualification for use of the device 102 to provide noninvasive glucose measurements is dependent upon the interaction with the data processing center 606. For example, FIG. 7 and its disclosure relates to a protocol for qualifying or preparing a processing device 102 for use non-invasively.

[0066] FIG. 7 illustrates a simplified measurement process or protocol 700, according to an embodiment of the present disclosure. In an embodiment, the protocol 700 includes Step 702 where a patient qualifies for noninvasive glucose measurements. Some research suggests that only around seventy percent (70%) of possible patients qualify for noninvasive glucose measurements. Disqualification can be the result of many things, in particular optical density coupled with poor digit perfusion. Thus, in an embodiment, the device 102 may drive the light source 510 of the sensor 104 and receive optical absorption data. Based on the signal strength and/or quality of the data, the device 102 may request the user place the sensor on a different digit. Reasons for poor performance include finger thickness, pigmentation, perfusion, temperature, or the like. In some cases, the device 102 determines one or several ideal digits through the testing of each one for noninvasive measurements. In other embodiment, once the device 102 finds a sufficient digit, it recommends use of the that one. Through, for example, the determination of potential signal strength of the optical signals received from the sensor 104, the device 102 may pre-qualify a user as a candidate for noninvasive glucose measurements. Full qualification may not occur at all or at least until much of the protocol 700 is completed.

[0067] The protocol 700 also includes Step 704, where the device 102 enters a calibration phase. During calibration, many invasive measurements, such as strip measurements are taken. In an embodiment, during this step, noninvasive measurements are not displayed as they are not sufficiently calibrated for a particular user. In an embodiment, about twenty (20) to about sixty (60) invasive measurements are performed during up to about thirty (30) days. In an embodiment, the user takes noninvasive measurements with each of the inva-

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sive measurements in order to associate instrument readings with invasive results. While providing a guideline for the calibration process, the protocol is not meant to be limited thereby. The device **102** uses a certain number of measurements over a certain time to develop a reliable calibration. Some users will enthusiastically provide multiple measurements, perhaps many measurements per day. Other will only provide a minimal number, such as one or two measurements per day. The calibration process length will be longer for the latter than it will for the former.

[0068] In an embodiment, because of the difficulty associated with cross subject variability in the calibrations process, e.g., the process of mapping noninvasive instrument readings with glucose values, in an embodiment, the device originates with a general calibration or in some cases, no calibration at all. The user begins taking measurements and uploads the measurements to the data processing center **606**. After sufficient measurements, such as, for example, about twenty (20) to about one hundred (100) or so over about twenty (20) to forty five (45) days, the data processing center **606** will begin to see a convergence of the patient-specific calibration. In one sense, the mappings will begin to stabilize. For example, over that time period it is anticipated that the about minimums and about maximums start to fill in with patient specific correlations between noninvasive measurements and invasive measurements and the mapping functions will start to look more similar to the previous mappings. When sufficient convergence and/or stabilization occurs or begins to occur, the center **606** may download the patient-specific calibration to the device **102**.

[0069] The measurement process **700** also includes Step **706**, where the device **102** enters a verification phase. During verification, invasive measurements, such as strip measurements are taken, to ensure that the calibration has converged. For example, in an embodiment, the data processing center **606** has downloaded a patient specific calibration to the device **102**. Accordingly, the device generates optical absorption data, associated strip readings, and from its downloaded calibration, noninvasive glucose measurements. These now three associated pieces of data can advantageously be uploaded to the data processing center **606** and the newly found noninvasive glucose measurements can be verified as being accurate according to the expected and downloaded patient-specific calibration. Thus, advantageously, in Step **706**, the protocol proves or verifies that the device **102** is generating acceptable and accurate noninvasive glucose measurements and otherwise functioning properly. In an embodiment, the data processing center **606** reduces the data storage requirements for the device **102** by storing the data associated with the calibration protocol remote from the device **102**. In other embodiments, the process **700** may occur entirely within device **102**, or with other access to remote data systems.

[0070] In an embodiment, during Step **706**, verification, noninvasive measurements are not displayed as they may still be in need of further calibration for a particular user. In an embodiment, about one (1) to about two (2) invasive measurements should be performed per day for up to about five (5) days. In an embodiment, the user takes noninvasive measurements with each of the invasive measurements in order to associate instrument readings with invasive results.

[0071] The protocol **700** also includes Step **708**, where the device **102** enters a sustaining or maintenance phase. During this phase, invasive measurements, such as strip measure-

ments are taken, to ensure the calibration has not drifted from previous calculations. In an embodiment, during this step, noninvasive measurements are displayed as frequently as they are taken. In an embodiment, invasive measurements can be about one (1) week apart.

[0072] The measurement process **700** also includes Step **710**, where the device **102** compares current noninvasive measurements to determine whether such measurements are outside expectations. For example, in an embodiment, the device **102** uploads measurement data to the processing center **606**. As disclosed above, such information may advantageously include noninvasive glucose measurements and corresponding optical absorption data sets measured by the sensor **104**. The data processing center **606** may advantageously use the glucose measurements alone, or with additional physiological information about the user, to retrieve more generalized or stored optical absorption data sets associated with that measurement. For example, when the device **102** measures 125 mg/dL glucose and uploads that to the center **606**, the center **606** may advantageously retrieve stored optical absorption data sets associated with 125 mg/dL. These stored sets may be idealized, generalized, specific for the user, or combinations of the above. The stored data sets are then statistically compared to the uploaded data set from the device **102** associated with its measurement of, for example, 125 mg/dL glucose. The statistical comparison may be a Gaussian comparison or other statistical comparisons that provide an indication of how similar are the data sets, e.g., the stored data set and the uploaded data set, each associated with a similar or same glucose measurement, in this case, 125 mg/dL glucose. When the sets begin to be sufficiently dissimilar, the center **606** may inform the device **102** that the measurements are no longer within expectations and the device should be recalibrated. In an embodiment, recalibration can be a full recalibration or a partial recalibration or simply a restart of one of the other phases.

[0073] FIG. 8 illustrates a simplified minimally invasive strip measurement process **800** according to an embodiment of the present disclosure. The process **800** includes Step **802**, where a strip with the user's blood is inserted into the strip reader. In Step **804**, a medical application wakes up and takes priority of any necessary shared resources in the processing device **102**. The reader determines an output and forwards the output measurement to the medical application. In Step **806**, the application may determine to optionally display the result, particularly when the result indicates an abnormal condition or a trend is moving toward an abnormal condition. In Step **808**, the application determines whether a noninvasive measurement is desired, such as, for example, when the device **102** is performing a calibration or other phase, where, for example, timewise-commensurate minimally and noninvasive measurements are desired. In Step **810**, the application may prompt the user to begin a noninvasive sensor measurement process, such as process **900**, disclosed herein. In Step **812**, the application may determine to optionally display the minimally invasive result, particularly if the result was not displayed above. In an embodiment, the application may display both results, only one result, a result in which there is an associated higher confidence, or a combination of the results. In Step **814**, the measurement values are uploaded to one or more remote data processing centers. Other information may also be uploaded, such as, for example, spot check purchasing information, version information, demographic information, device information, use information for the device, the sen-

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sor, and/or the cable, or the like. In Step 816, the application may determine that the center is ready to download information to the device 102. For example, the center may have updated calibration information based on current or previous uploads, other users uploads, the calibration may be beginning or actually stabilizing and/or converging, or the like. Moreover, the center may download spot check purchasing information, other application information, or the like.

[0074] FIG. 9 illustrates a simplified noninvasive sensor measurement process 900 according to an embodiment of the present disclosure. The process 900 includes Step 902, wherein if not already, the user wakes up the medical application. In Step 904, the user attaches the sensor 104 to a digit and activates a test input, such as a button on the touch screen of the device 102. In Step 906, the device 102 processes the detector signals to determine noninvasive glucose measurement values. In Step 908, the application determines whether the device 102 has been sufficiently calibrated with invasive measurements. If not, the application requests in Step 910 that an invasive measurement be taken. In Step 912, even when the device 102 is sufficiently calibrated, additional less frequent invasive measurements may be recommended to ensure accurate noninvasive performance. In Step 914, the application determines whether the processed noninvasive measurement is within expectations. In an embodiment, the device may include limits for its calibration, may include data sets for certain calibrations, may include confidence indicators for particular measurements based on, for example, the optical signal processing, or the like to understand whether current measurements are outside expectations. In Step 916, the application displays, when appropriate, the noninvasive measurements. In Step 918, the measurement values and/or other information are uploaded to one or more remote data processing centers. In Step 920, the application may receive information from the data center.

[0075] FIGS. 10-19 illustrate exemplary user interfaces of the processing device of FIG. 1, according to various embodiments of the present disclosure. As shown in many of the user interfaces, familiar smart phone icons may be used such as, for example, battery power, time, connectivity such as Bluetooth or Wi-Fi, 3 G or higher connectivity, cellular connection signal strength such as increasing bars, and the like. Additionally, in the case of a spot check device, the device may include a readily identifiable indicator for the amount of measurements remaining or otherwise paid for. For example, FIG. 10 shows a "220" with a green check to indicate the user has prepaid or otherwise received 220 spot check measurement credits.

[0076] Moreover, FIG. 10 illustrates an exemplary test result interface, which may advantageously show the available scale, the severity at each end of the scale in alternating colors, such as, for example, green when the measurements are normal, yellow on each side as they move away from normal and red where measurements are abnormal.

[0077] FIG. 11 illustrates an exemplary bar graph interface which may, for example, show readings during different activities for a particular time period. For example, FIG. 11 shows a collection of readings before and after meals, and numerically provides a combination of those readings. In an embodiment, the combination is a simple average. In other embodiment, the combination may be more statistically sophisticated and/or appropriately weight confidence indications associated with particular readings. In an embodiment, the scale at the bottom of the interface shows the time period

of the combination, such as, for example, the simple average. In this case, the user has selected to average 14 days. As shown, the user could select days, months, or years, and then slide the bar for a numerical value of the same, and the processing device 102 would combine the stored measurement values over the corresponding time for display in similar fashion. Other activities around which one may wish to summarize measurement values may include exercise, snacks, specific dietary intake, times of day or week, or the like.

[0078] FIGS. 12A-12B illustrate exemplary result and trend interfaces. For example, FIG. 12A may show basic information for noninvasive measurements, along with a trend showing readings over time. The trend may advantageously include flags for entered activities, may highlight abnormal or trending toward abnormal behaviors. In the particular embodiment shown, the round points indicate noninvasive measurements and the triangle points indicate strip or otherwise invasive measurements. Moreover, the trend may be selectable to review information available for the selected point in time. An activity log may also be shown. FIG. 12B may show similar basic information for invasive measurements, and switch the location and/or color to ensure a user can readily recognize the difference between the display of invasive and noninvasive values. Other icons or text may also be used to distinguish the measurements, such as, for example a blood droplet and/or triangle to indicate a strip measurement being displayed.

[0079] FIGS. 13A-13D illustrate exemplary trend interfaces. FIG. 13A illustrates an exemplary single trend of glucose measurements. In an embodiment, the trend may show both invasive and noninvasive measurements or may include trend lines for each type. Also, the trend line timeframe, or displayed time period, may be configurable through, for example, a pinch or dual finger parting to respectively shorten or lengthen the time period. FIG. 13B illustrates exemplary trends of multiple parameters, in this case, glucose and blood pressure, over the same time period so that, for example, a caregiver can readily recognize or identify how events in the multiple physiological parameters affect a particular parameter. For example, the user could readily review whether spikes or falls in blood pressure have any correlation to glucose readings. FIG. 13C illustrates how many normal, approaching abnormal, and abnormal measurements were taken over a period of time. FIG. 13D shows that additional information can be viewed when selecting a particular set of values, in this case, the set of abnormal measurements. As shown, the user selected a particular time period, and within that time period, the user selected the abnormal readings. Thus, the device 102 displays the measurement data, such as value, date, time, or the like, associated with each abnormal reading in the set.

[0080] FIGS. 14A-14B illustrate exemplary calibration protocol interfaces. Particularly, FIG. 14A shows a user their progress through a calibration protocol, such as the protocol shown in FIG. 7. In an embodiment, the information displayed may include time and date of last calibrations and next calibrations, may include information on how many calibrations have been accomplished and/or how many remain. FIG. 14B illustrates how the applications can guide a user through a calibration process. For example, a timeline may advantageously indicate where in a calibration process the current measurements fall. Moreover, the timeline may include days, months, and years tabs to quickly organize information regarding device usage.

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[0081] FIGS. 15A-15D illustrate exemplary alarm interfaces according to embodiments of the disclosure. In FIG. 15A, a measurement may indicate that a user's glucose levels are low and may indicate an alarm by any of placing an icon, such as a bell, on the display, enclosing the display in a red square, and/or highlighting on a trend graph the low measurement. In some embodiments, the bell is placed low when the glucose levels are abnormally low, or high, when they are abnormally high (FIG. 15B). Other more traditional visual and/or audio alarms may also be used including flashing display items or sounding audible alarms, the intensity or frequency of which might vary to show severity. In FIG. 15B, a measurement may indicate that a user's glucose levels are high. In FIG. 15C, abnormally high measurements may trigger a message to see a physician immediately, contact emergency services, check ketone levels or the like. Moreover, additional icons, such as ringing multiple bells, or other icons may be used to show significant severity. In FIG. 15D, a delta alarm may indicate the direction of change. For example, a low glucose level that is trend-wise dropping, indicates a more dangerous condition than one that is trend-wise raising. Icons and other information may be highlighted to indicate these conditions.

[0082] FIGS. 16A-16C illustrate exemplary instructive interfaces, such as test strip insertion guidance (FIG. 16A), general information about glucose measurements and glucose normality ranges (FIG. 16B), or pricing information for instrument usage (FIG. 16C). In FIG. 16A, the instructive interface may also guide the user in calibrating or verifying strip reader measurements. For example, often strip reader manufacturers provide solutions for testing strip readers. The user drips solution onto a test strip and inserts the strip into the reader. The solution is designed to cause the reader, when functioning properly, to provide a measurement within a provided range of acceptable measurements. These solutions will often include three bottles corresponding to low, regular or medium and high solutions, designed to cause the reader to provide measurement in the low, medium and high ranges. The interface may guide the user through, for example, using these solutions to verify accurate operation of the strip reader.

[0083] In FIG. 16C, the user may interact with the device to purchase additional spot checking credits. Spot checking accounting is disclosed in U.S. Pat. App. Pub. No. 2011-0172498, filed Jul. 14, 2011 titled "Spot Check Monitor Credit System," incorporated by reference herein.

[0084] FIG. 17 illustrates an exemplary application interface showing, for example, different types of medical and nonmedical applications that might be executed by the processing device 102. For example, the applications may include noninvasive and minimally invasive glucose testing, internet browsing, email, texting, video conferencing, cellular phone, graphs, activities or calendaring, flag or activity management, weather, photographs or videos, camera or video operation, calibration protocols, electronic interference detection, such as that disclosed in U.S. is disclosed in U.S. Pat. App. Pub. No. 2011-0109459, filed May 12, 2011 titled "Interference Detector for Patient Monitor," incorporated by reference herein, music, spot check purchasing applications, such as those disclosed above, general questions and setting preferences, facebook, twitter, map or navigation, address book, internet bookmarks, downloadable applications of all sorts, and the like.

[0085] FIGS. 18A-18B illustrate an exemplary events interfaces including a food flag interface. One application that

may be extraordinarily helpful for, for example, a diabetic trying to manage their glucose levels is to include easily entered activities into a calendar program. These activities or flags are associated with events such as fasting, insulin, food/drink intake, measurement, exercise, and the like. FIG. 18B shows an exemplary interface presented when the user wants to enter an eating activity. As shown, the information may include the amount of carbohydrates in the food, the portion or size, the glycemic index or the like. As is understood by an artisan, the glycemic index includes ranges of about fifty five (55) or less for most fruits and vegetables, legumes/pulses, whole grains, nuts, fructose and products low in carbohydrates, about fifty six (56) to about sixty nine (69) for whole wheat products, basmati rice, sweet potato, sucrose, baked potatoes, and about seventy (70) or above for white bread, most white rices, corn flakes, extruded breakfast cereals, glucose, maltose.

[0086] FIGS. 19A-19B illustrate exemplary priority interfaces. As will be disclosed in more detail below, certain applications will be designed to take a priority over other applications. In general, medical applications, such as those of FIG. 19A, will take priority over others, such as those of FIG. 19B. Moreover, in an embodiment, the order the icons appear within a figure may visually provide the user with an understanding of their priority. For example, in FIG. 19B, incoming phone activity takes priority over incoming email activity, etc. In an embodiment, the manufacturer sets the medical priorities over the nonmedical priorities. In an embodiment, the user may be able to add applications to one or both priority interfaces to reorder default priorities; however, the default priorities for certain applications may not be editable to ensure safe operation of the device.

[0087] FIG. 20 illustrates a priority mode processing device having medical related functions and non-medical related functions sharing common resources. Advantageously, the processing device has a priority mechanism so as to prevent the medical related functions from competing with the non-medical related functions for the common resources during critical time periods. These critical time periods are indicated by triggering events. In particular, a triggering event indicates to the system that the medical related functions have resource priority. This priority may be, for example, exclusive access to and use of displays, alarms, controls, communications and processing power so as to make time critical patient health and risk assessments and output those assessments in a timely manner to a healthcare provider.

[0088] FIG. 21 illustrates a priority mode processing device embodiment having a smart phone or other cellular communication device sharing one or more common resources with a processing device. The common resources may include operating system functions, processor cycles and input/output access, to name a few. A priority mode for the processing device may be triggered by the connection or disconnection of a device to the monitor, such as a sensor or sample, advantageously giving the monitor maximum access to processing and input/output resources so as to respond to physiological data inputs and calculate medical parameters or conditions accordingly.

[0089] FIGS. 22A-22D are illustrations of priority mode glucometer embodiment. The glucometer is advantageously integrated in a handheld device having both processing device and smart phone capabilities. When a sensor or test strip is plugged or inserted into the handheld device, it is usable as a glucometer. When the sensor or test strip is unplugged or

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removed from the handheld device, it is usable as a mobile phone, such as, for example, a smart phone with many of today's smart phone applications and functions.

[0090] FIGS. 23-29, described in detail below, illustrate various embodiments that combine processing device and smart phone features in an advantageous manner so that the physiological measurements are not interrupted or delayed by smart phone functions, such as incoming calls and text messages to name a few.

[0091] FIG. 23 illustrates processing device embodiment that utilizes a KVM (keyboard/video/mouse) switch for priority control. The KVM switch controls access to the display, touchscreen and audio between a processing device CPU that runs the medical system and a smart phone CPU that runs the cell phone system.

[0092] FIG. 24 illustrates a processing device embodiment where the medical functions are implemented as a single application running on the smart phone operating system (OS), such as those offered by Google (Android), Windows, Apple, or the like. In an embodiment, when a sensor or strip is plugged into the device, the OS activates the medical application and all other applications are suspended and cannot be resumed until the sensor/strip is unplugged or some other user supplied input is provided.

[0093] FIG. 25 illustrates a processing device embodiment where two separate operating systems run as virtual machines on the device CPU. The cell phone OS handles cell phone functions and the medical OS handles the medical system functions.

[0094] FIG. 26 illustrates a processing device embodiment where the medical application runs next to the cell phone OS (e.g. Android). As soon as the sensor or strip is plugged into the device, the medical application is started and runs separate from the cell phone OS. The cell phone OS is suspended and the medical application takes control of the hardware, including the touch screen.

[0095] FIG. 27 illustrates a dual-boot processing device embodiment. As soon as a sensor or strip is plugged into the device, the cell-phone operating system is shut down and the device is rebooted into the medical operating system.

[0096] FIG. 28 illustrates a double-sided processing device embodiment. A first display is mounted on one side of the device with cell-phone functionality and a second display is mounted on the other side of the device with medical functionality. A related embodiment implements two separate systems (cell-phone and medical) in one (hardware) chip, such as a FPGA or ASIC.

[0097] FIG. 29 illustrates a processing device embodiment where the cell phone as (e.g. Android) runs a single medical system application while a sensor and/or strip is plugged into the device. When the sensor or strip is removed, the OS runs in a normal al operating mode, multitasking various applications.

[0098] A priority mode processing device has been disclosed in detail in connection with various embodiments. These embodiments are disclosed by way of examples only and are not to limit the scope of this disclosure. One of ordinary skill in art will appreciate many variations and modifications.

[0099] In an embodiment, the features and functionality of the processing device 102 may be incorporated into smart phone technologies. For example, a smart phone may enable patients and healthcare personnel to manage health data, and

in particular, physiological reading data from one or more health data collection devices such as a glucose sensor or pulse oximeter.

[0100] FIG. 30 illustrates an exploded view of a smart phone including internally integrated processing capability, such as, for example, a processing board or other device. As shown, the technology board 3000 comprises an integrated board within the smart phone housing. The board communicates with an external optical sensor, such as sensor 104. In various embodiments, the sensor provides an output signal indicative of an amount of attenuation of predetermined wavelengths (ranges of wavelengths) of light by body tissues, such as, for example, a digit, portions of the nose or ear, a foot, or the like. The predetermined wavelengths often correspond to specific physiological data desired, including for example, blood oxygen information such as SpO₂, blood glucose, total hemoglobin, methemoglobin, carboxyhemoglobin, bulk tissue property measurements, water content, pH, blood pressure, respiration related information, cardiac information, indications of perfusion, or the like. The smart phone may also include software such as an application configured to manage output measurement data from the processing board. The application functionality can include trend analysis, current measurement information, alarms associated with below threshold readings or reminders to take measurement data at certain times or cycles, display customization, iconic data such as hearts beating, color coordination, bar graphs, gas bars, charts, graphs, or the like, all usable by a caregiver or smart phone user to enable helpful and directed medical monitoring of specified physiological parameters.

[0101] The smart phone may advantageously be capable of connecting to and receiving data from a physiological data collection device such as an optical sensor glucose sensor. The smart phone is able to connect to a data collection device and receive data from the device. The smart phone may be configured to analyze data from the device, display data from the device, and otherwise utilize the data to empower the user to take control of his health.

[0102] The smart phone may have a fully integrated technology board which receives and analyzes data from the collection device. The technology board may alternatively be housed within a removable cartridge. The board may employ RF shielding. The smart phone may utilize a Samsung GHz processor or the like. The processor may utilize mDDR2 or mDDR, or the like. In some embodiments, the processor may employ MLC NAND 48 TSSOP flash memory technology or the like. The smart phone may comprise a power management integrated circuit with on/off/wakeup capability.

[0103] In an embodiment, the smart phone may utilize one of a number of different operating systems. For example, an android, linux, or qnx system may be used.

[0104] Software may be installed upon the smart phone that can analyze the data received from the sensor device and make it available in a way for the user to manage his health. There may be software which allows a user to view the data in a multitude of ways. The smart phone may also be able to alert the user to an abnormal data reading. The software may also alert the user to take a physiological reading or medication. It may have the capability of sending physiological data to a home computer where the user manages his health data. The data can also be sent to a physician or pharmacist for their expertise and feedback.

[0105] The smart phone through the board may include an input that can connect to the data collection device or optical

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sensor. In some embodiments this sensor may be on the top portion of the smart phone, integrated into the smart phone housing or housing attachment, or a separated device as shown. The connector may be chosen from a variety of connectors including a snap click connector, a magnetic connector and/or a multi pin connector. In some embodiments, the smart phone may comprise a magnetic latch sensor port with dual orientation with allows for a controlled break away. In an embodiment, the sensor includes active pulse technology designed to provide a perturbation of the tissue during measurements.

[0106] The smart phone may have a display that is between about 3" and about 5" or more. A bigger screen may advantageously allow more versatility from a user experience perspective. The display may have the capability of switching between a portrait and a landscape mode based on user preference or automatically based on positioning. The display, in some embodiments, has a wide viewing angle in both portrait and landscape mode. It may have a backlight in one of both of the modes. In some embodiments, the resolution is around about 960x640 with a 24 bit rate.

[0107] The display may be a projective capacitive LCD screen. The screen may be made from impact resistant materials such as Gorilla Glass®, sapphire crystal or polycarbonate. The conductive coating may be made of a variety of materials including indium tin oxide (ITO). The screen may be a multi input screen with 3 or more inputs. The screen may also support gestures such as an x/y swipe inertia scroll, presshold, 2 point pinch zoom, 3 point pinch zoom and swiping. In some embodiments, the smart phone is capable of utilizing haptic technology to communicate with the user. This feature may be useful to alert a user to significant changes in physiological measurements. The device may also utilize a bezel to maneuver around the display.

[0108] The smart phone may comprise a power button. The button may be a tactile button that produces an audible click. The button may be located on a side of the smart phone.

[0109] The smart phone may include a chargeable battery to provide power to the device. In some embodiments, the battery may be a 1500-3000 mAh lithium battery. The battery may be housed in a recess of the smart phone covered by a removeable battery door. This may be located on the back of the phone.

[0110] The smart phone may additionally comprise an AC power input. In some embodiments, the input is located on a side of the device. Alternatively, the device may be inductively charged.

[0111] The smart phone may also comprise one or more USB ports. The ports may be regular or micro USB ports. The ports may utilize a USB switch such as a Fairchild switch. The USB port may be capable of charger detection, audio and UART detection. The USB ports may be located on a side of the smart phone.

[0112] The smart phone may be capable of wireless communication. This may be achieved through a wireless connection such as a Broadcom 802.11 a/b/g/n dual band connection. It may also utilize a Bluetooth connection, an FM receiver using an RDS standard, or the like. The smart phone may also comprise a module to allow for connectivity to networks such as the 3G network, 4G network, and the like.

[0113] The smart phone may contain a speaker and/or an earphone jack located on it. In some embodiments, the speaker is a multi-directional speaker for audio over air. The speaker may be capable of 85 db. The smart phone may

further comprise an amplifier. The amplifier may be a 3W filter-free class D mono audio amplifier in some embodiments. A volume control may be located on the phone. In some embodiments, the volume control may be a volume rocker switch.

[0114] The smart phone may comprise a camera. The camera may be a video and/or still camera. The smart phone may contain a camera on the front side and rear side of the phone to enable things like self-portraits and video chats. In some embodiments, the front camera is a 1.3 MP camera. In some embodiments, the back camera is an 8 MP camera. The camera(s) may also comprise a flash which may be an LED flash.

[0115] Some or all of the part of the device not making up the screen may be comprised of a variety of materials including liquid metal, CNC aluminum, and Hydro Formed aluminum. Soft touch paint may be applied.

[0116] The smart phone may comprise high durometer bumper fins to protect it from drops and everyday wear and tear. The fins may comprise a material that is not temperature sensitive, has a generally high chemical resistance, is flexible, and is durable. In some embodiments, this material may be multi-shot santoprene or another thermoplastic elastomer. The fins may be located on the rear side of the smart phone, at the top and bottom of the device. There may be between 1 and 5 fins located on both the right and left sides of the smart phone. The fins may extend towards the top of the device and wrap around to cover a portion of the top of the device. The bottom fins may be designed in a similar manner.

[0117] The foregoing features are not intended to be exhaustive. The smart phone may contain additional features such as an acoustic speaker slot, a slot for Micro SD, HDMI outputs, a microphone, a sim card draw, an accelerometer and the like.

[0118] FIG. 31 illustrates insertable cartridges that may connect to, for example, a technology board or other interface on a general purpose smart phone. As shown in FIG. 31, the insertable cartridge may be function specific. It could be a glucose sensor cable cartridge. A glucose sensor may be integrated into the cartridge. The cartridge could alternatively be a temperature and blood pressure cartridge. The cartridge may be an environmental sensor, for instance, measuring CO in parts/million. It may be an extra battery cartridge. The cartridge may be a barcode scanner or other digital device interface for data import, software, application firmware upgrades or patient management. The cartridge could also provide general oximetry or cooximetry functionality and sensor connectivity, or may be acoustic sensor compliant and determine respiration parameters.

[0119] The smart phone device described may advantageously allow a user to carry only one unit rather than both a phone and a sensor device. As a result of its dual functionality, the device may be bigger and more costly than a traditional smart phone. Additionally a user may have to replace their existing phone. Another advantage is that the smart phone to be used as an 'on the go' health organizers. This setup also allows the user more technology options. For example, glucose readings as well as pulse oximetry readings may be received by the smart phone device. It is also easier to input information using the smart phone device, particularly when the user has to re-calibrate the device on a weekly basis.

[0120] In another embodiment of the smart phone device, the technology board with the integrated data collection device may be a separate unit from the smart phone. In FIGS. 31-34, the smart phone may include a wireless chipset (FIG.

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32) that communicates with stand-alone data collection devices (FIG. 33-34). The stand-alone devices may provide functionality similar to any individual or combination of the cartridges mentioned in the foregoing. The wireless chipset may provide UWB, Bluetooth, Zigbee, and wireless USB connectivity.

[0121] The stand-alone units provide for smaller more portable smart phones. Additionally, the user has the option to carry the smart phone and sensor device together or separately, which could be less cumbersome. In some embodiments, the units may include a display. The unit may communicate with a smart phone to better present measurement information, processed information, and/or trend information to a user on more advanced smart phone displays. The unit may be capable of wireless communication with any mobile phone or computer. The unit will need to be able to connect to an external computing device in order to calibrate.

[0122] One significant advantage of the smart phone embodiments is that the smart phone manufacturers, and not the medical device manufacturer, has invested the resources into developing and commercializing the processing used for nonmedical applications. Development of this hardware and software is thus lifted from a medical device focused company.

[0123] Although the foregoing processing device and smart phones have been described in terms of certain preferred embodiments, other embodiments will be apparent to those of ordinary skill in the art from the disclosure herein. For example, alternate protocols may be implemented or the like. Additionally, other combinations, omissions, substitutions and modifications will be apparent to the skilled artisan in view of the disclosure herein. Accordingly, the present invention is not intended to be limited by the reaction of the preferred embodiments, but is to be defined by reference to the appended claims.

[0124] All publications, patents, and patent applications mentioned in this specification are herein incorporated by reference to the same extent as if each individual publication, patent, or patent application was specifically and individually indicated to be incorporated by reference.

[0125] Moreover, terms used herein are intended to have their broad ordinary meaning understood within the art. The term "and/or" is intended to mean that one, any combination of two or more, or all combinations of the corresponding listed elements are appropriate; however, it is not intended to mean that all combinations must be accomplished.

What is claimed is:

1. A handheld processing device comprising:
an invasive glucose monitoring system;

a noninvasive glucose monitoring system, said noninvasive glucose monitoring system including one or more signal processors configured to communicate a drive signal to a light source configured to irradiate tissue of a user, said processor configured to receive one or more signals indicative of glucose in blood from at least one detector configured to detect said light after attenuation by said tissue, and configured to process said one or more signals to determine measurements of said glucose in said tissue; and

an application configured to receive glucose measurements from said invasive glucose monitoring system and said noninvasive glucose monitoring system and configured to output for display at least said glucose measurements from said invasive glucose monitoring system.

2. The processing device of claim 1, wherein said invasive glucose monitoring system comprises a strip reader.

3. The processing device of claim 1, comprising a communication interface.

4. The processing device of claim 3, wherein said communication interface is configured to communicate with a data processing center to receive calibration data.

5. The processing device of claim 4, wherein said communication interface is configured to communicate with a data processing center to send said glucose measurements.

6. The processing device of claim 1, wherein said application is configured to instruct a user in the performance of a measurement protocol involving invasive and noninvasive measurements.

7. The processing device of claim 1, wherein said processing device is at least a portion of a smart phone.

8. The processing device of claim 1, wherein said application is configured to take priority use of shared resources in said processing device.

9. A method of customizing a noninvasive glucometer for use by a user, the method comprising:

electronically collecting invasive glucose measurements with a glucometer;

electronically collecting noninvasive data sets indicative of noninvasive glucose measurements with said glucometer, said data sets responsive to light attenuated by tissue of said user;

electronically storing a mapping of said noninvasive data sets to glucose values; and

providing noninvasively derived glucose measurements to said user.

10. The method of claim 9, wherein said collecting invasive glucose measurements comprises reading a disposable strip.

11. The method of claim 9, wherein said collecting noninvasive data sets comprises activating a light source of a non-invasive sensor, receiving signals responsive to attenuation of light from said light source by said tissue, and electronically processing said signals.

12. The method of claim 9, wherein said storing said mapping of said noninvasive data sets comprises communicating with a remote processing device to download said mapping.

13. The method of claim 9, wherein said storing said mapping of said noninvasive data sets comprises uploading said data sets and said invasive glucose measurements to a remote processing device.

14. The method of claim 13, wherein said uploading includes uploading said noninvasive glucose measurements to verify operation of said glucometer.

15. The method of claim 9, comprising executing a medical application.

16. The method of claim 9, comprising executing a non-medical application.

17. The method of claim 16, comprising providing cellular phone communication.

18. A noninvasive glucometer, comprising:

a memory storing a calibration; and

a front end processor driving a light source to irradiate tissue of a patient, receiving signals responsive to attenu-

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ation of said light by said tissue, processing said signals to determine one or more measurements of glucose, said processing including accessing said calibration to associate a set of data values with glucose measurements, said calibration being customized for said patient by invasive glucose measurements of said patient's tissue.

19. The glucometer of claim 18, comprising a strip reader.
20. The glucometer of claim 18, comprising a communication module communicating with a remote processing device to receive said calibration after said invasive glucose measurements have been acquired.

* * * * *

EXHIBIT 17



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(12) **United States Patent**
Smith et al.

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(54) **MULTIPLE WAVELENGTH SENSOR EMITTERS**

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(Continued)

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(58) **Field of Classification Search**

None

See application file for complete search history.

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

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(21) Appl. No.: **17/028,655**

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Related U.S. Application Data

(63) Continuation of application No. 16/437,611, filed on Jun. 11, 2019, which is a continuation of application
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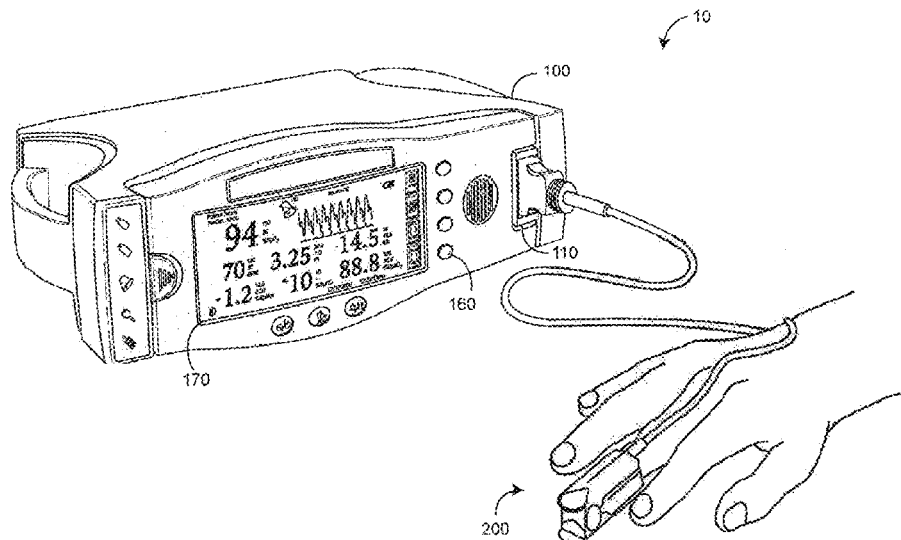
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(57) **ABSTRACT**

A physiological sensor has light emitting sources, each activated by addressing at least one row and at least one column of an electrical grid. The light emitting sources are capable of transmitting light of multiple wavelengths and a detector is responsive to the transmitted light after attenuation by body tissue.

(52) **U.S. Cl.**
CPC *G16H 40/67* (2018.01); *A61B 5/0022* (2013.01); *A61B 5/0205* (2013.01); *A61B 5/0261* (2013.01); *A61B 5/0295* (2013.01);

29 Claims, 48 Drawing Sheets



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Related U.S. Application Data

- No. 15/694,541, filed on Sep. 1, 2017, now Pat. No. 10,327,683, which is a continuation of application No. 14/472,760, filed on Aug. 29, 2014, now Pat. No. 9,750,443, which is a continuation of application No. 13/776,085, filed on Feb. 25, 2013, now Pat. No. 8,849,365, which is a continuation of application No. 12/422,915, filed on Apr. 13, 2009, now Pat. No. 8,385,996, which is a continuation of application No. 11/367,013, filed on Mar. 1, 2006, now Pat. No. 7,764,982.
- (60) Provisional application No. 60/657,281, filed on Mar. 1, 2005, provisional application No. 60/657,268, filed on Mar. 1, 2005, provisional application No. 60/657,759, filed on Mar. 1, 2005, provisional application No. 60/657,596, filed on Mar. 1, 2005.
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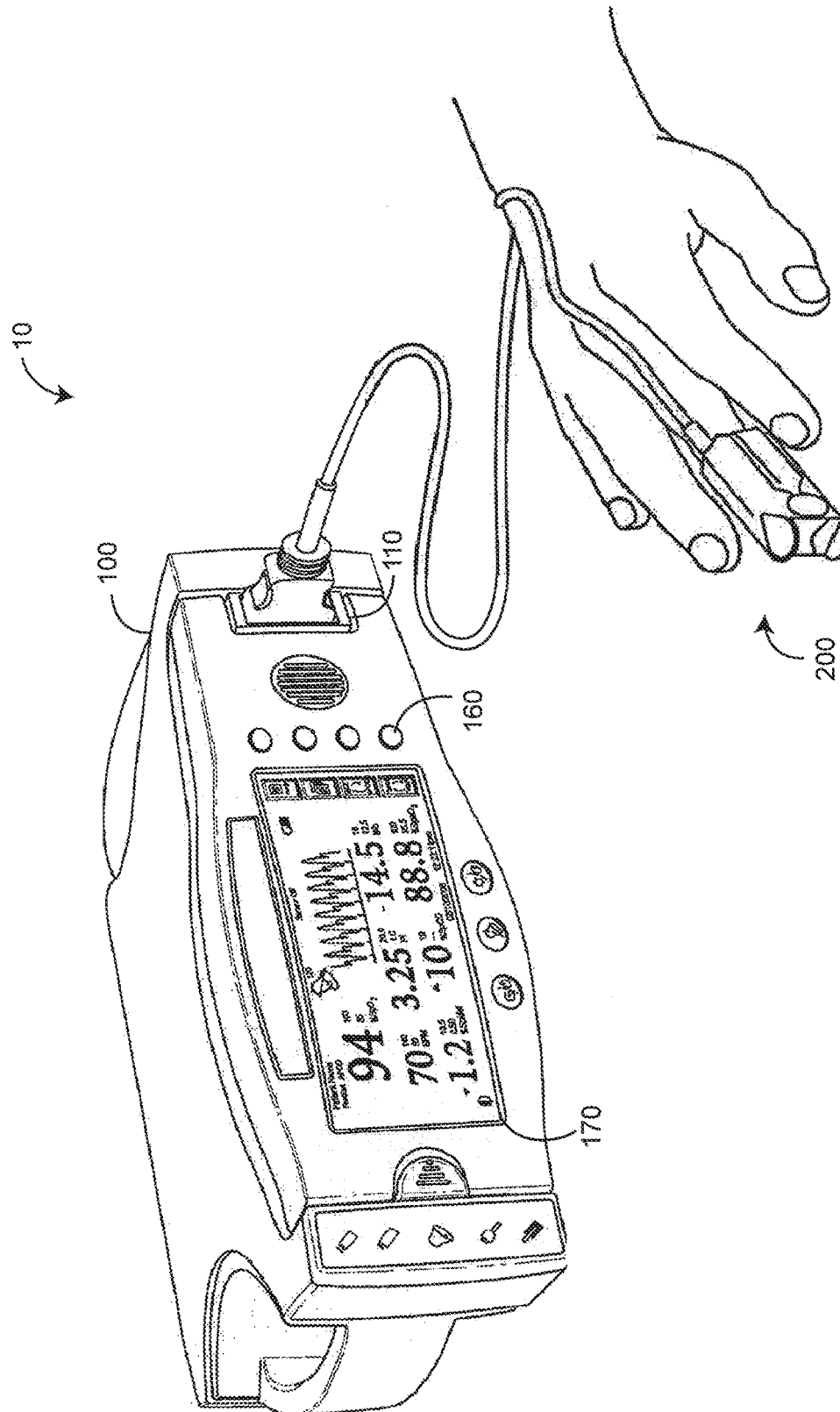


FIG. 1

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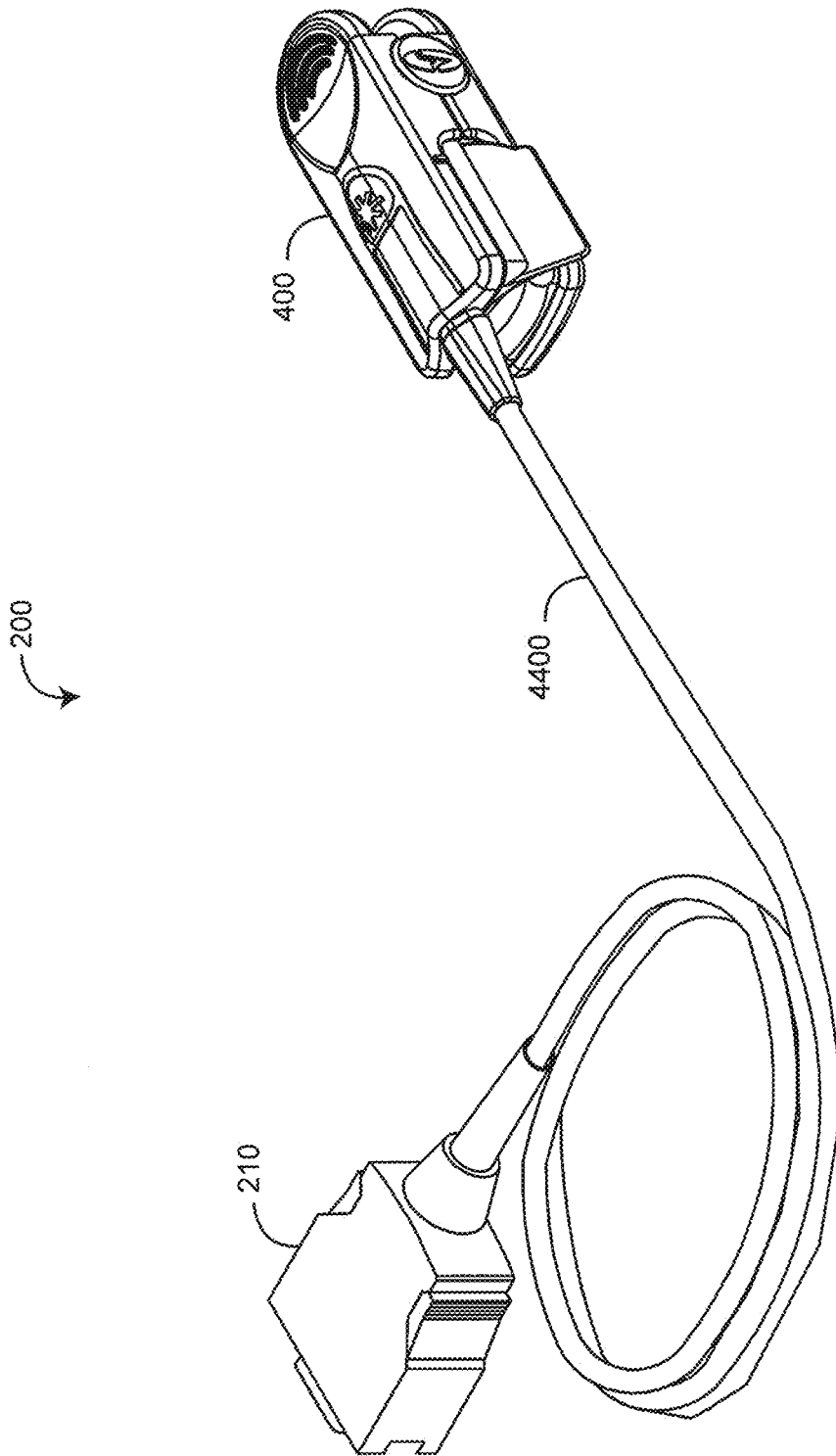


FIG. 2A

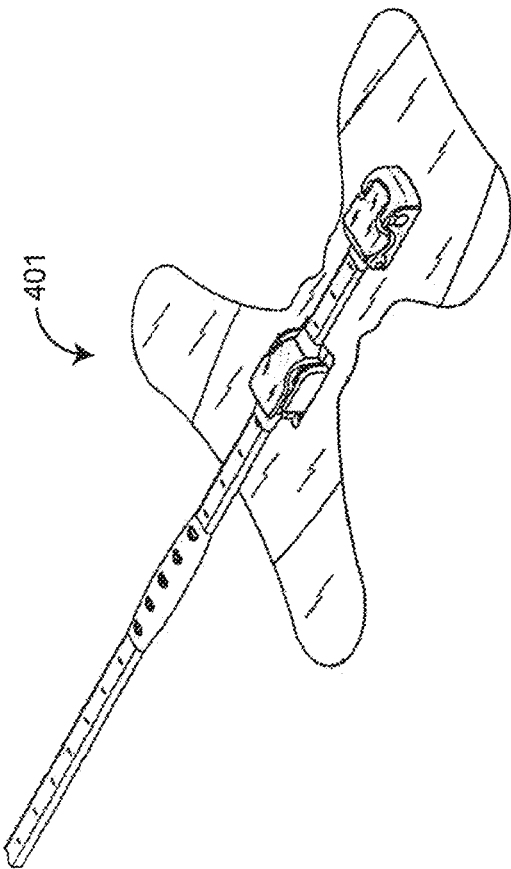


FIG. 2B

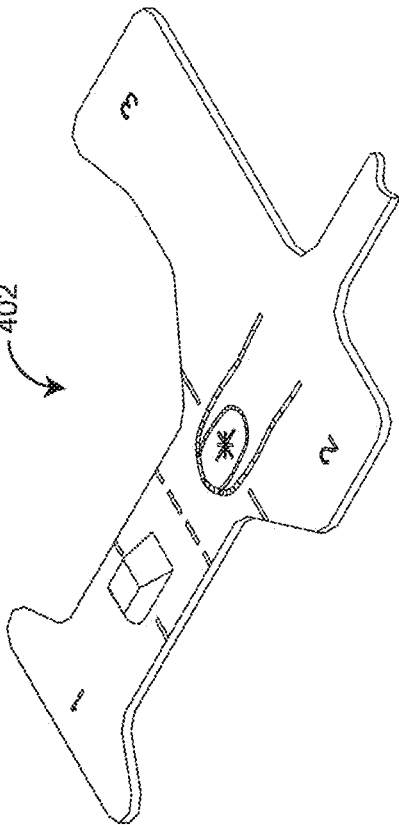


FIG. 2C

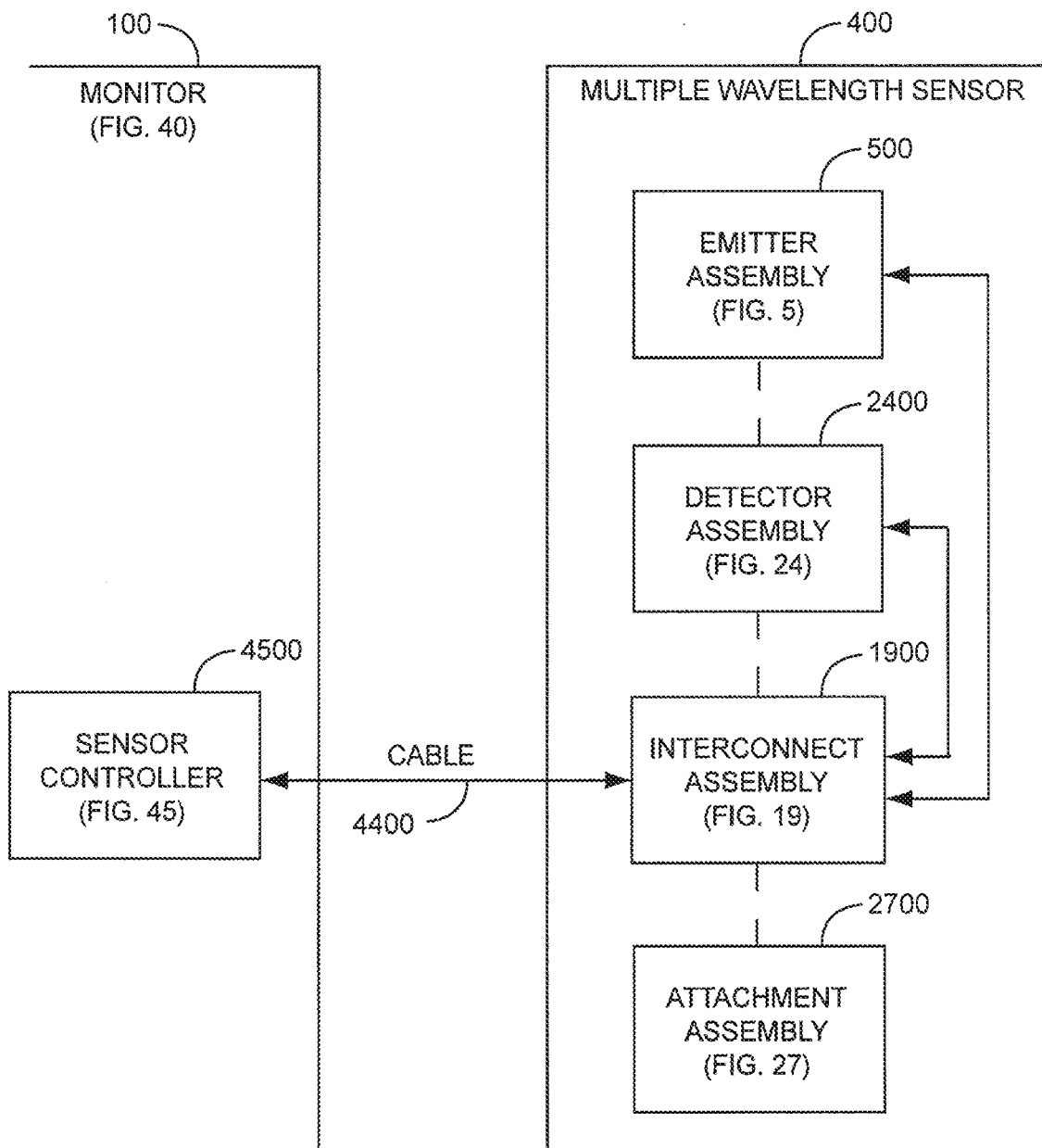


FIG. 3

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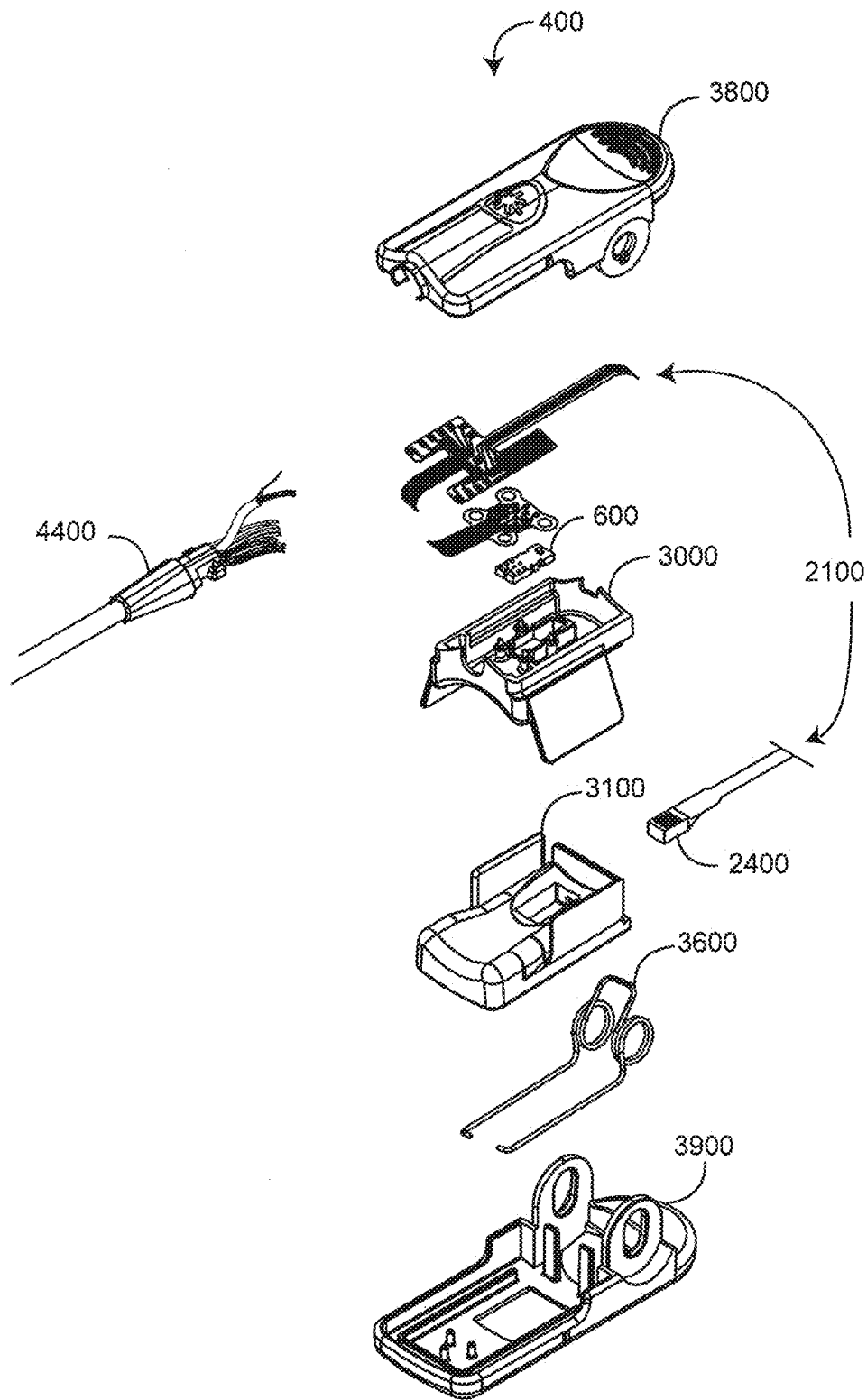


FIG. 4

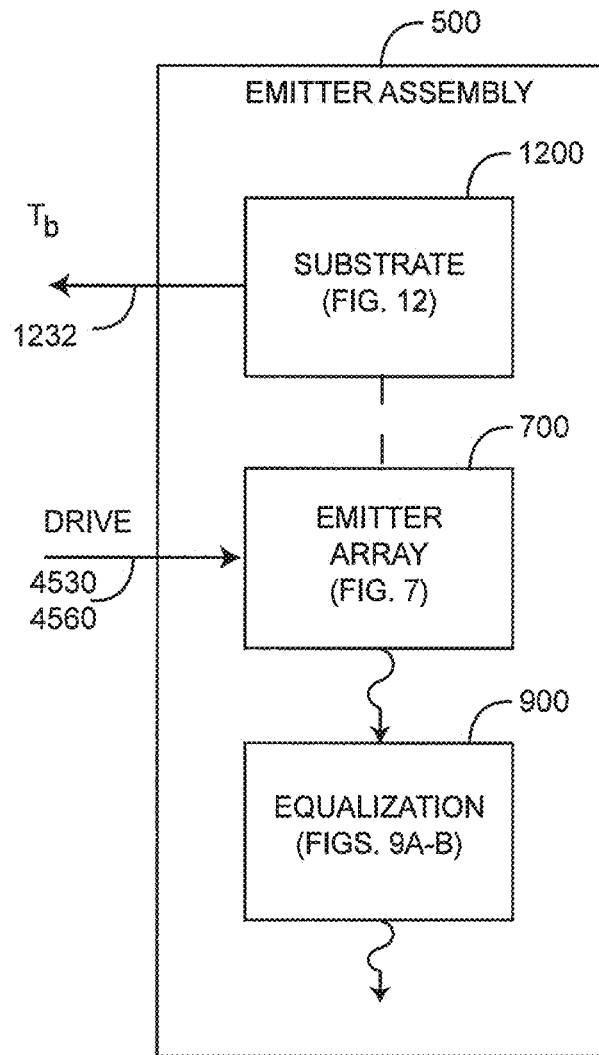


FIG. 5

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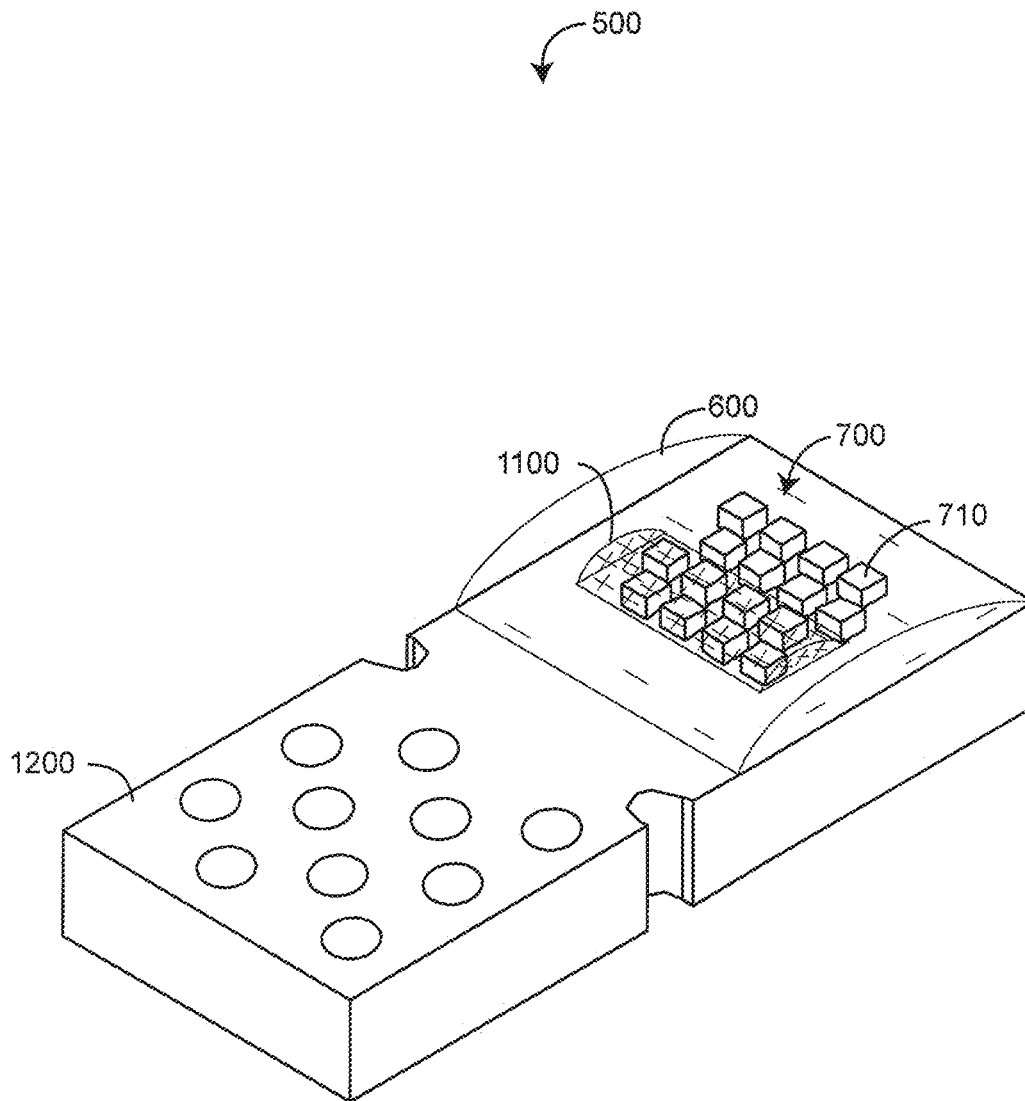


FIG. 6

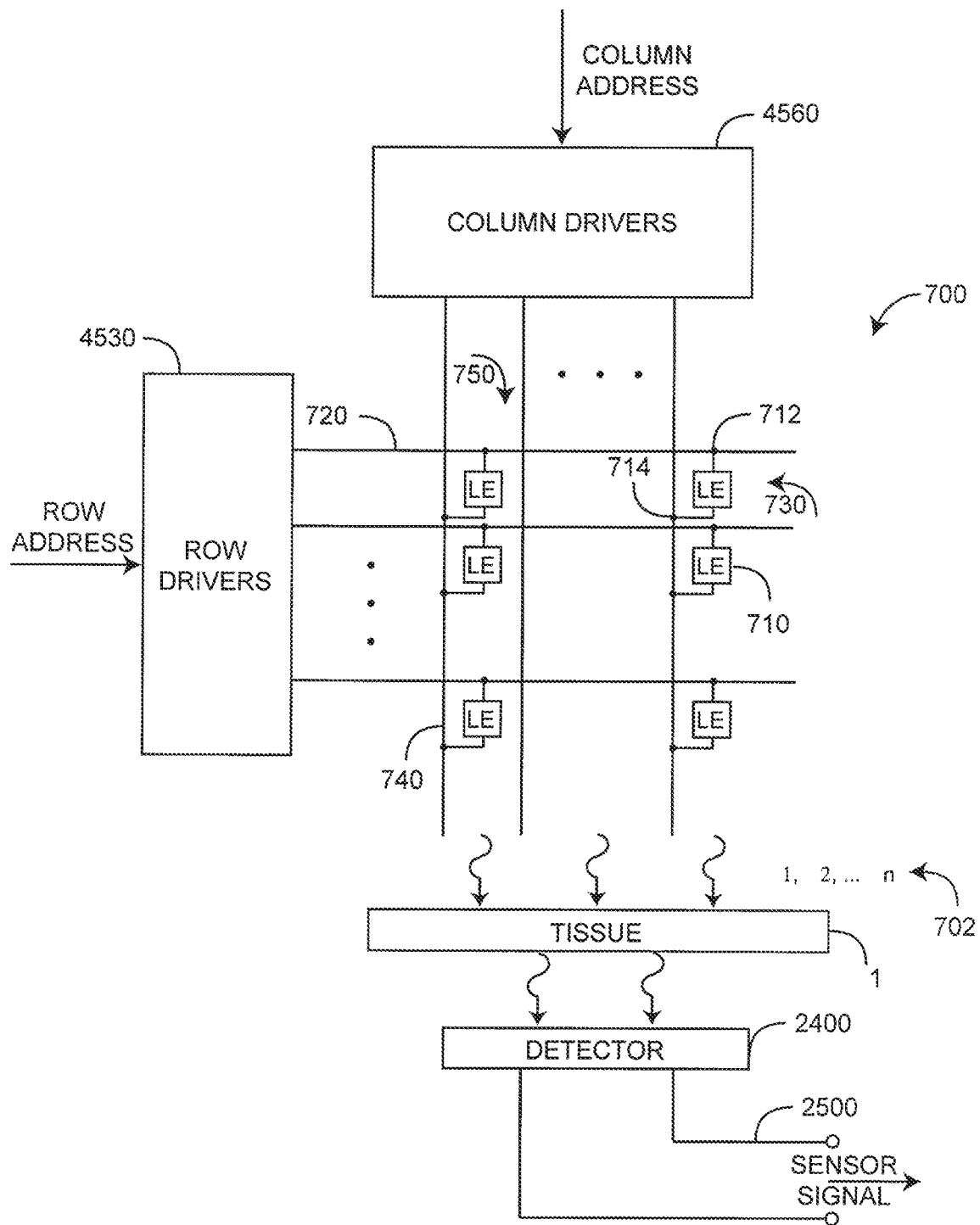


FIG. 7

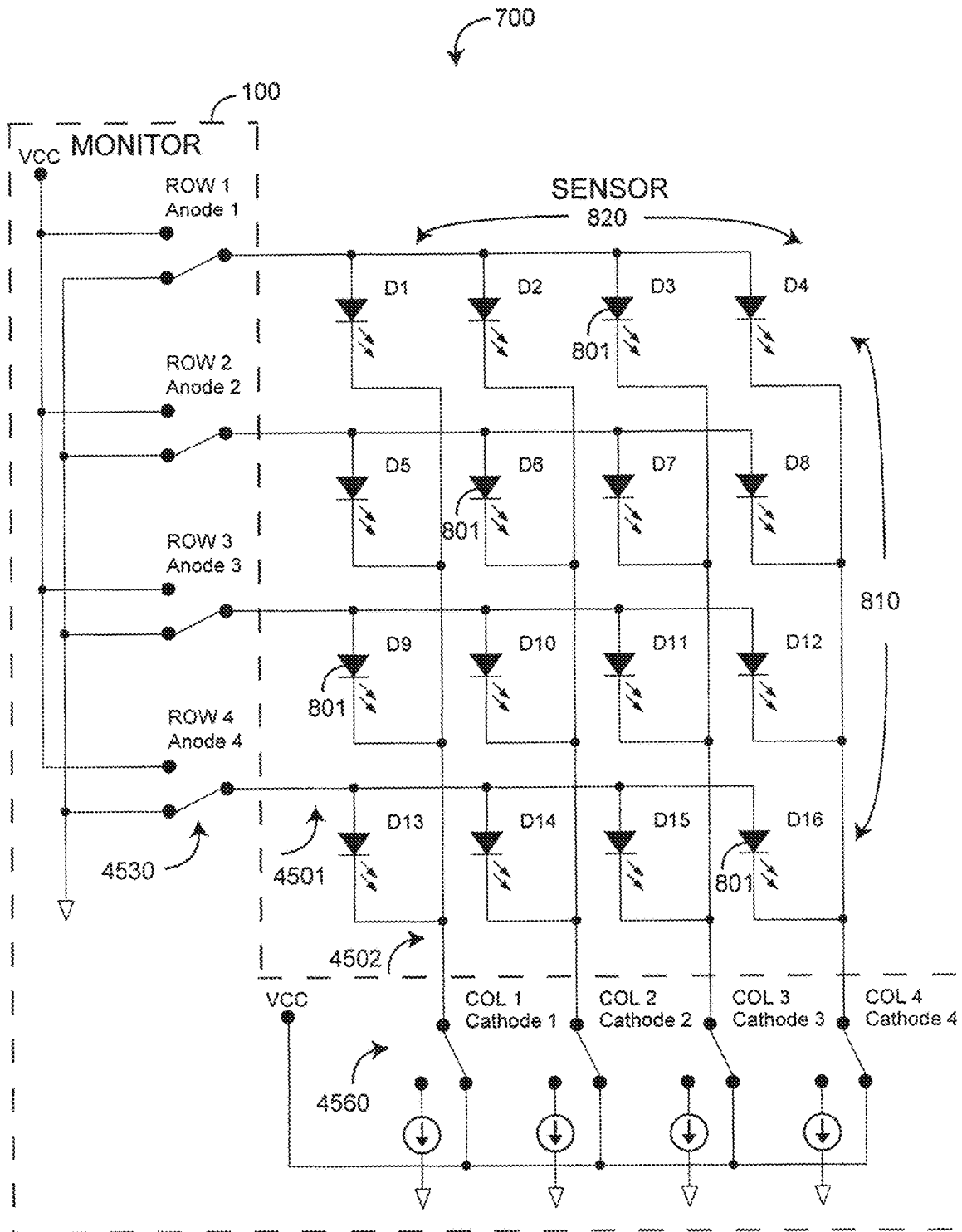


FIG. 8

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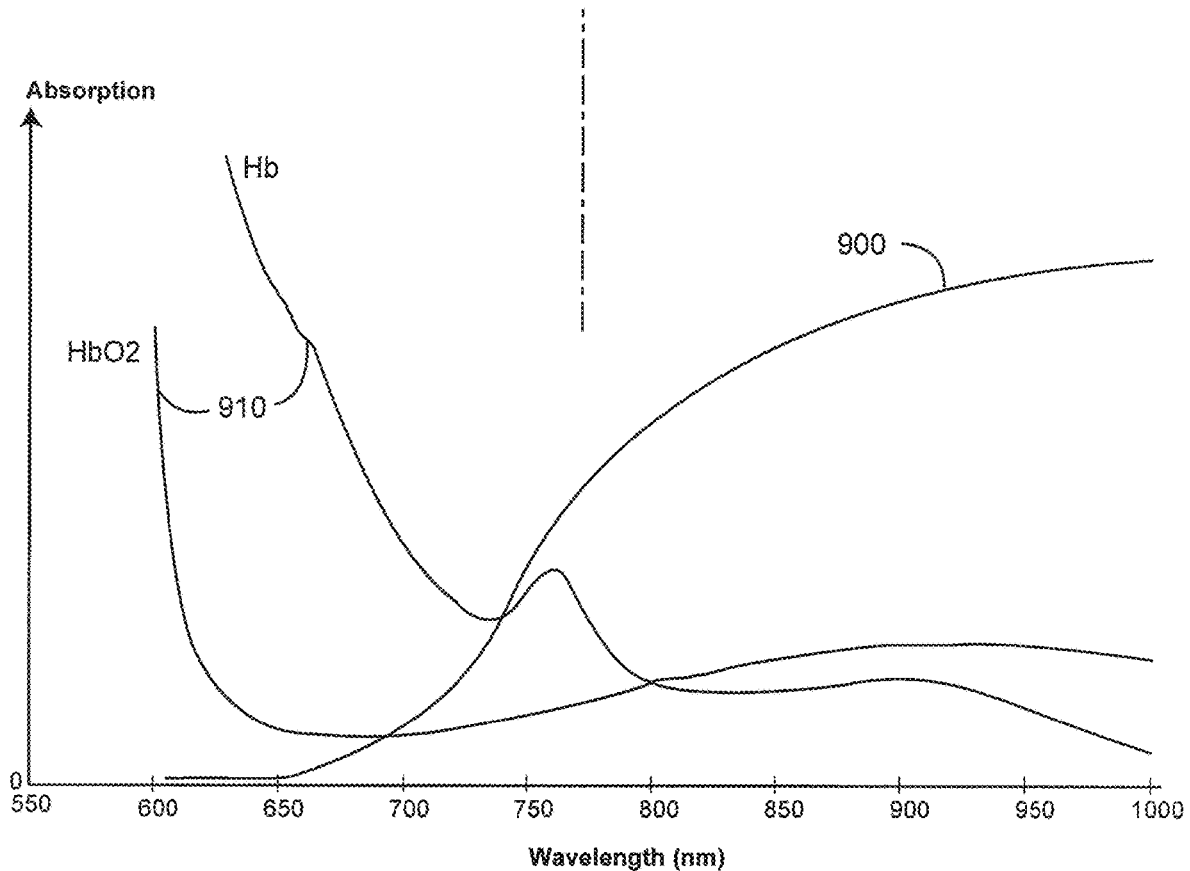
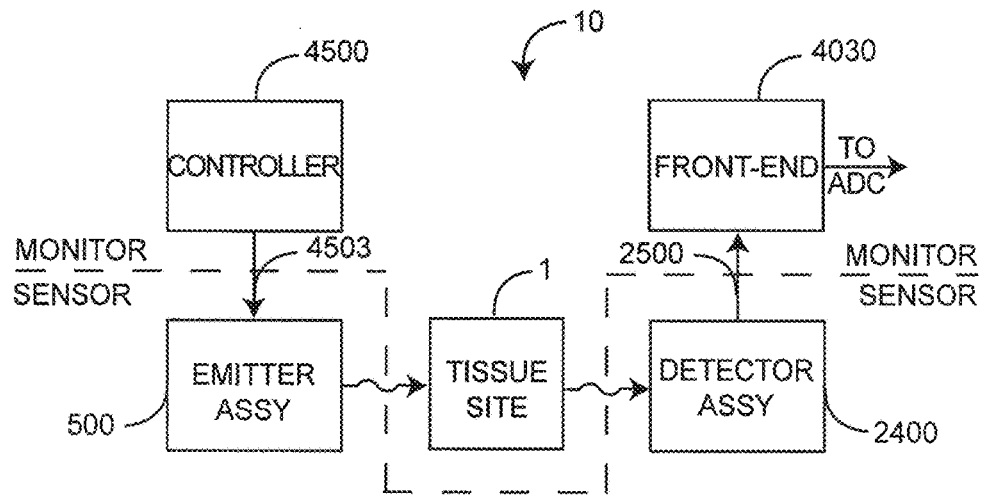


FIG. 9

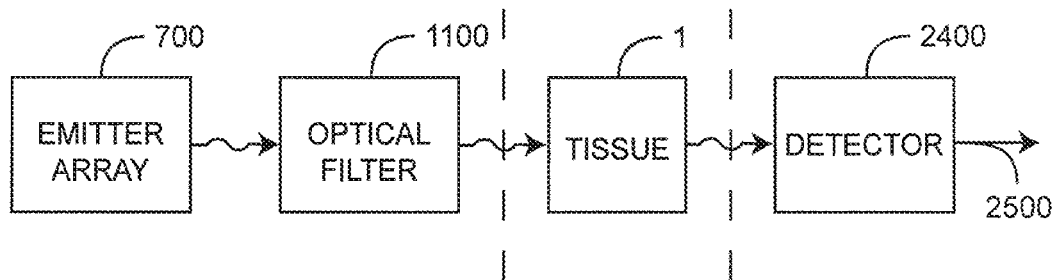


FIG. 10A

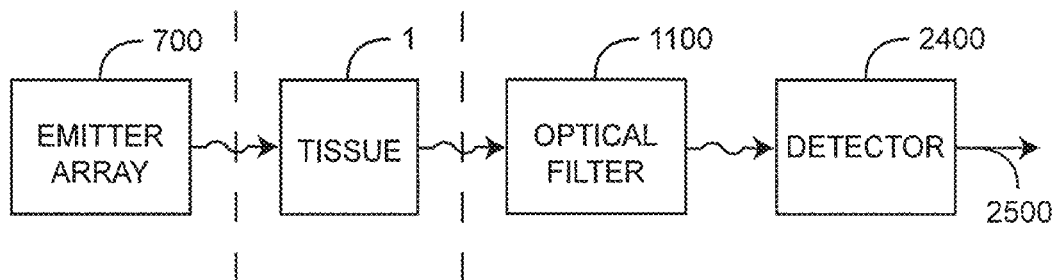


FIG. 10B

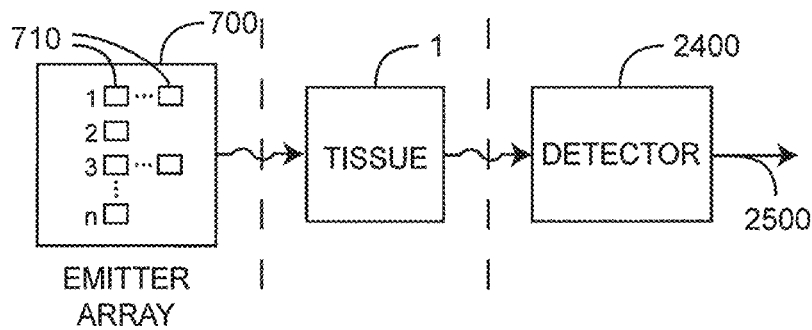


FIG. 10C

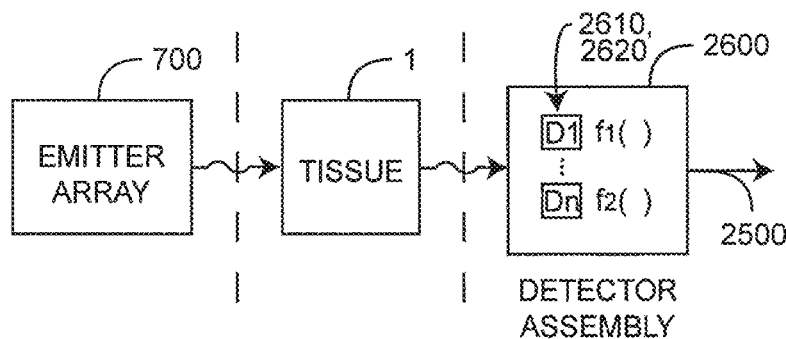


FIG. 10D

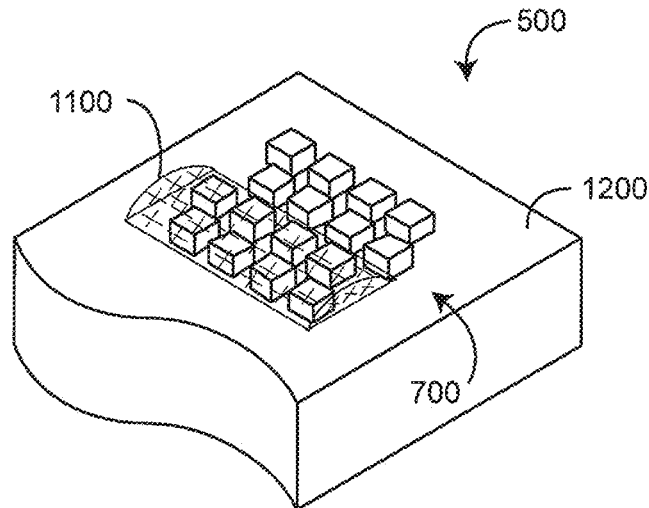


FIG. 11A

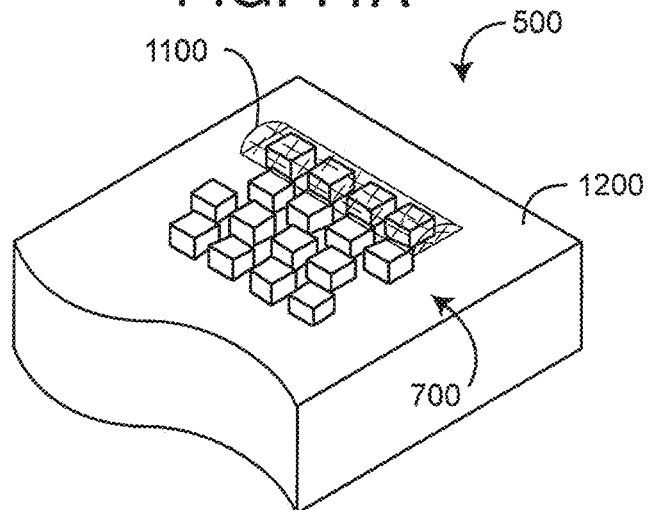


FIG. 11B

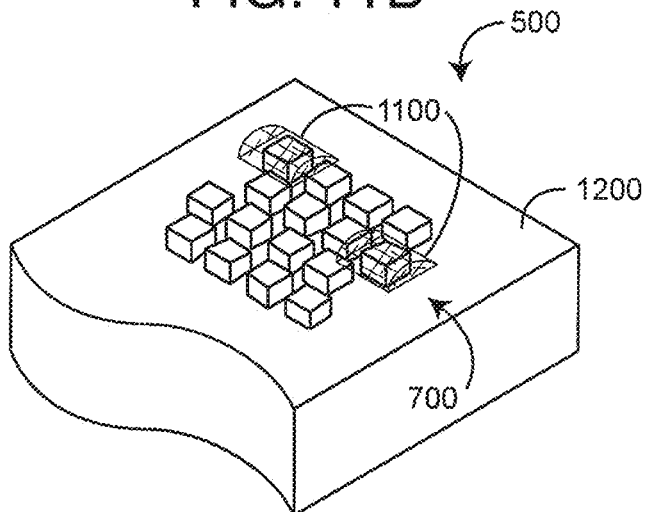


FIG. 11C

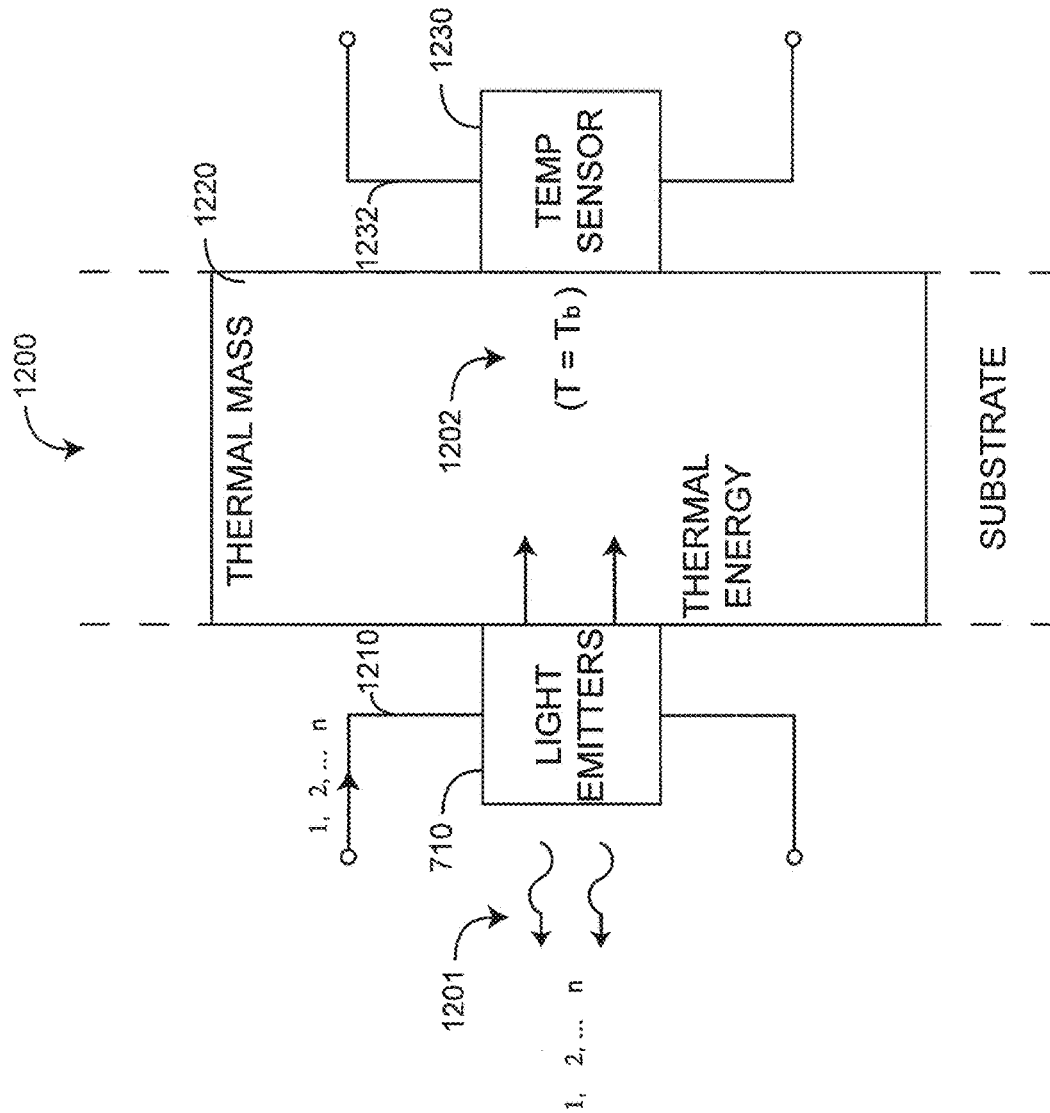
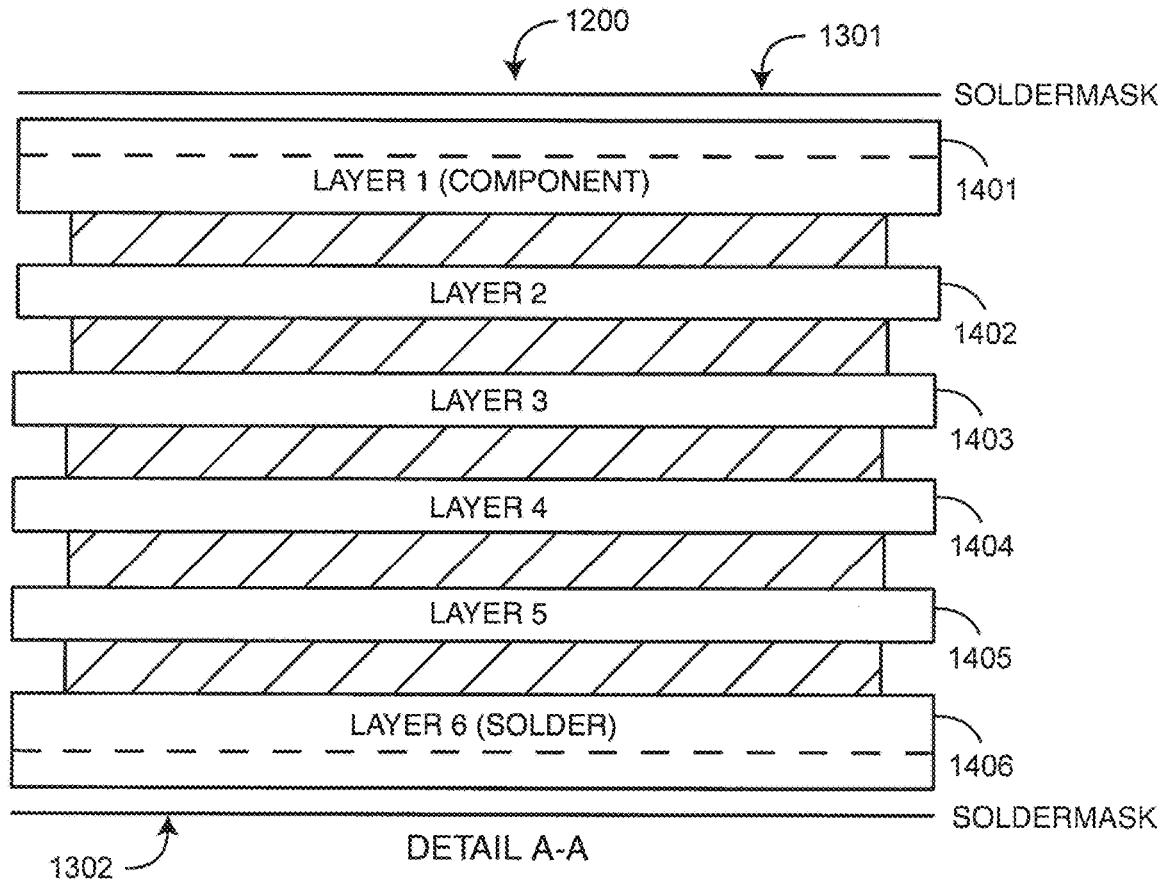
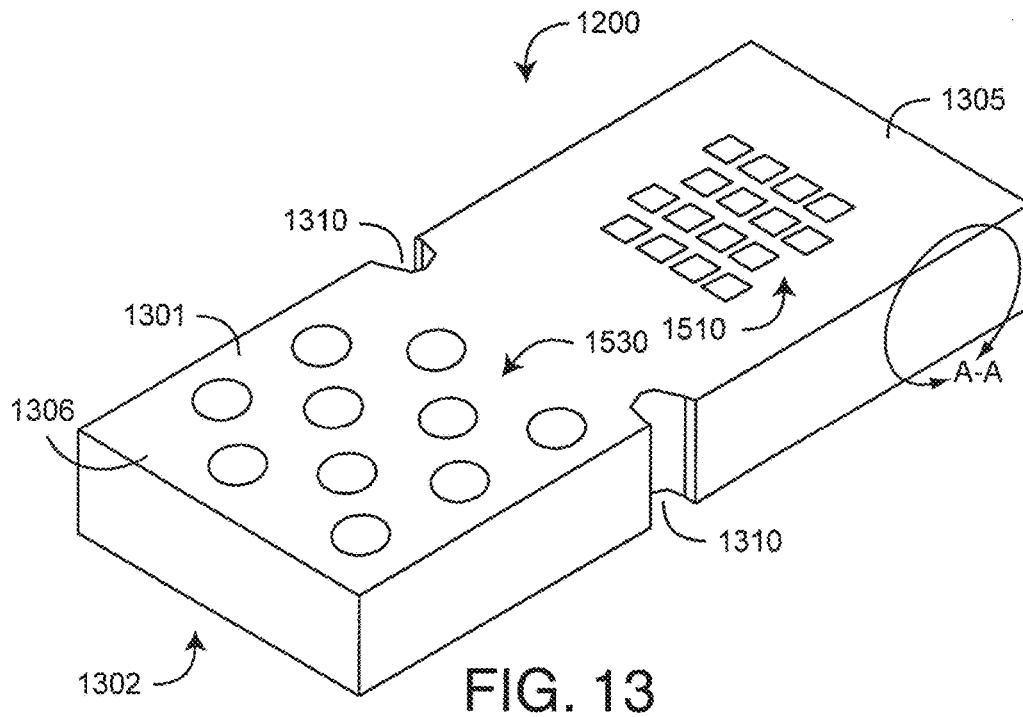


FIG. 12



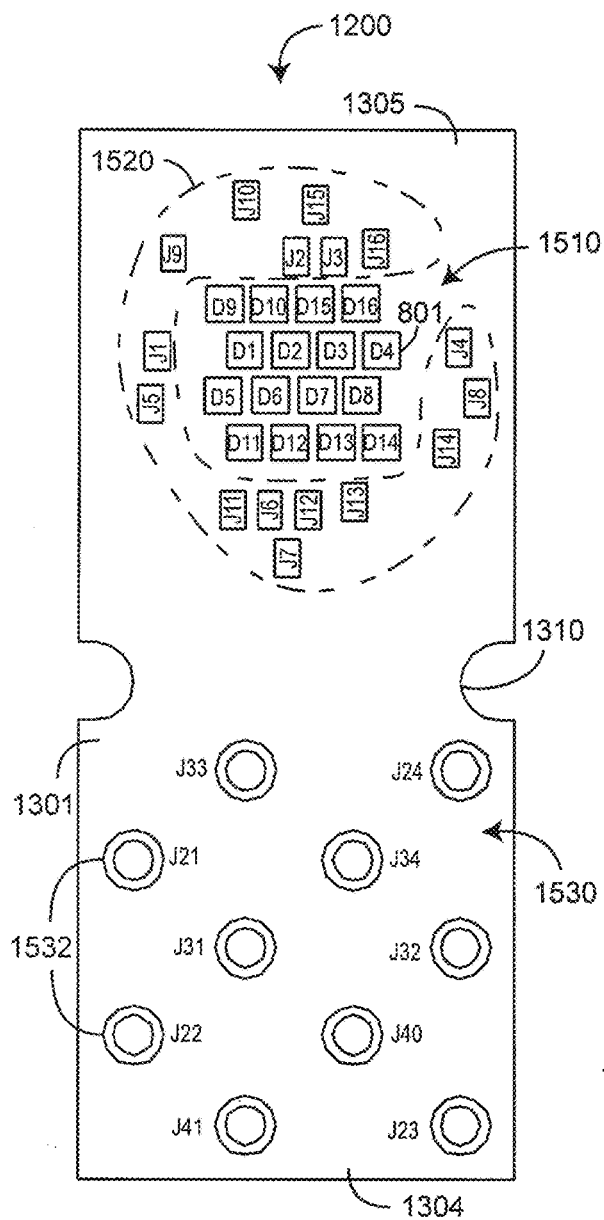


FIG. 15

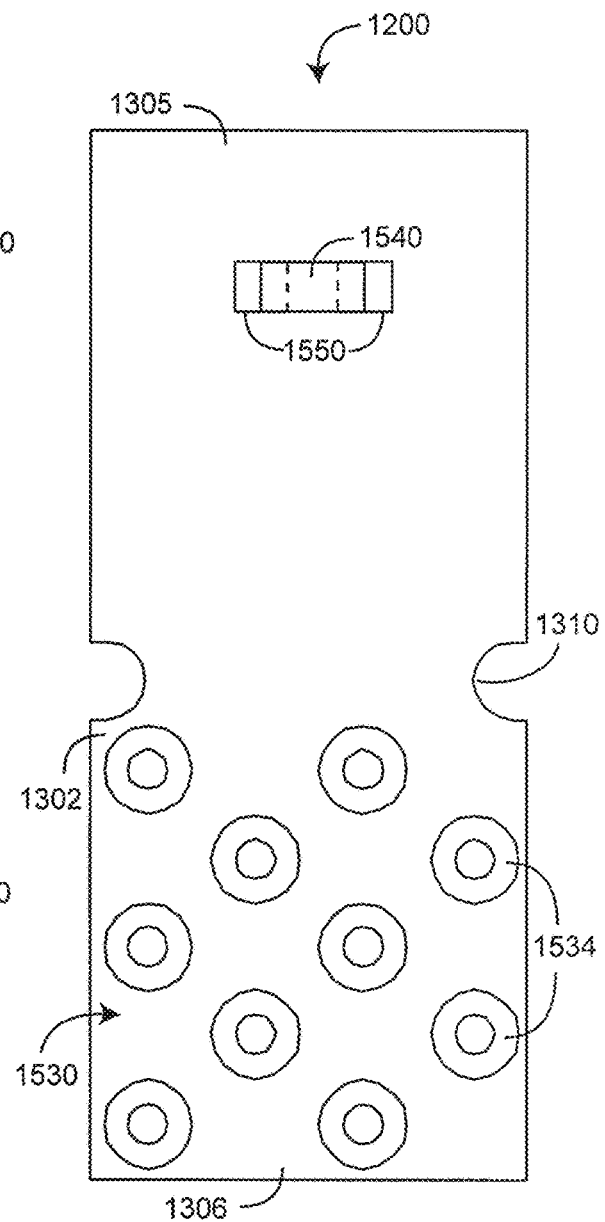
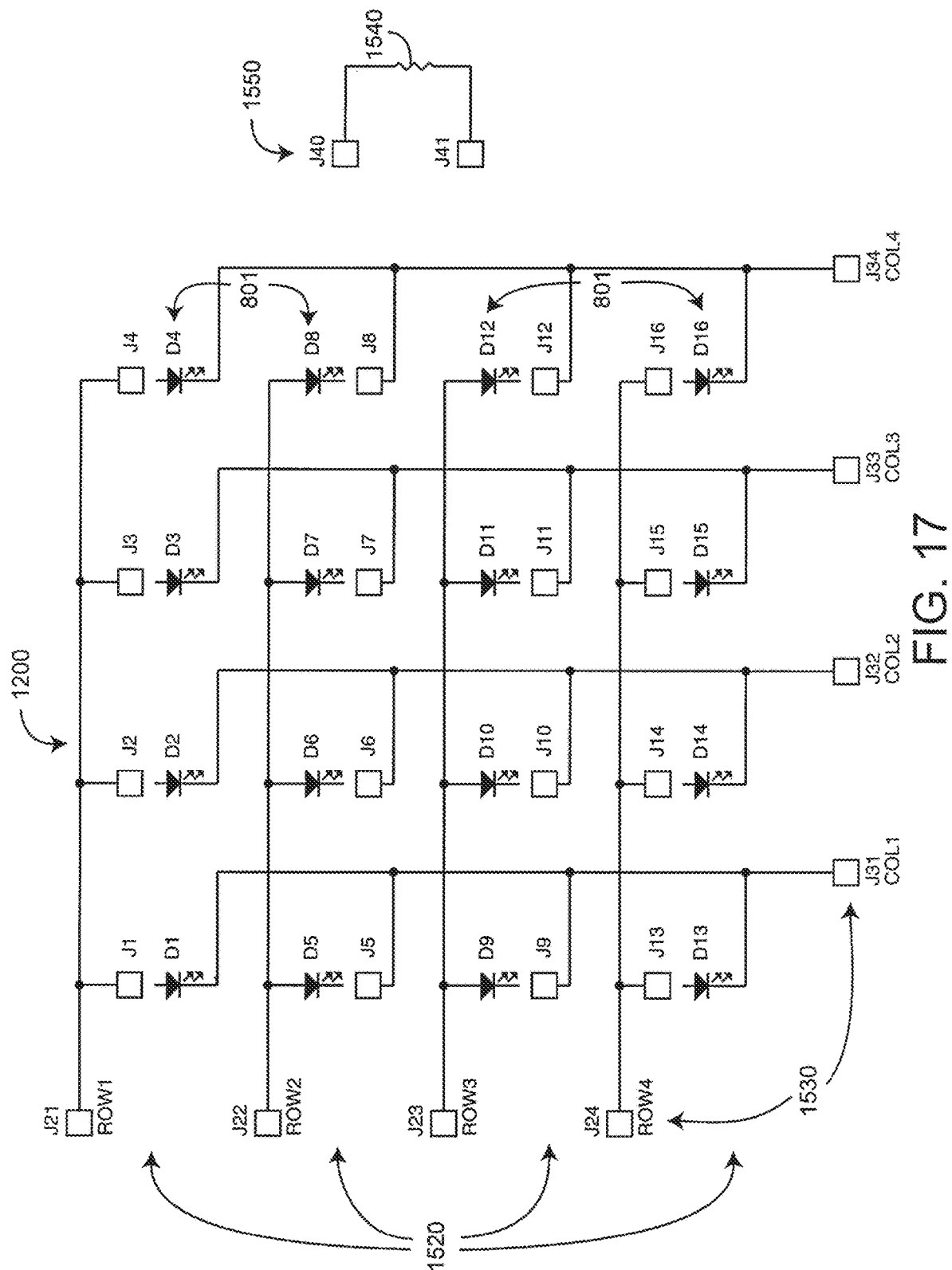


FIG. 16



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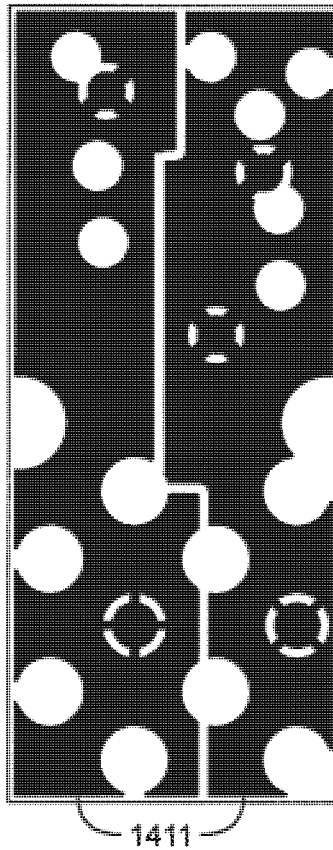



FIG. 18

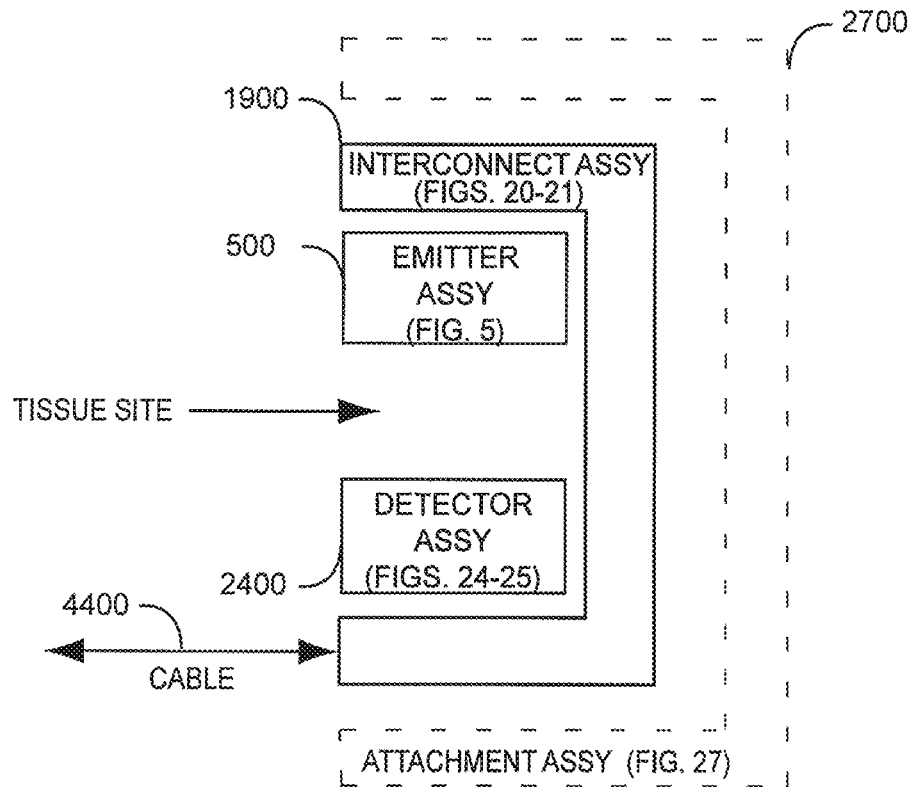


FIG. 19

FIG. 1 is a schematic diagram of a cable connector assembly 1900. The assembly includes a cable connector 2230 with a shield 2070. It is connected to a detector mount 2050 and an emitter mount 2210, which are part of a detector assembly 2400 and an emitter assembly 500, respectively. The entire system is mounted on a circuit substrate 2200. A cross-sectional view 4400 of the cable connector is shown on the left.

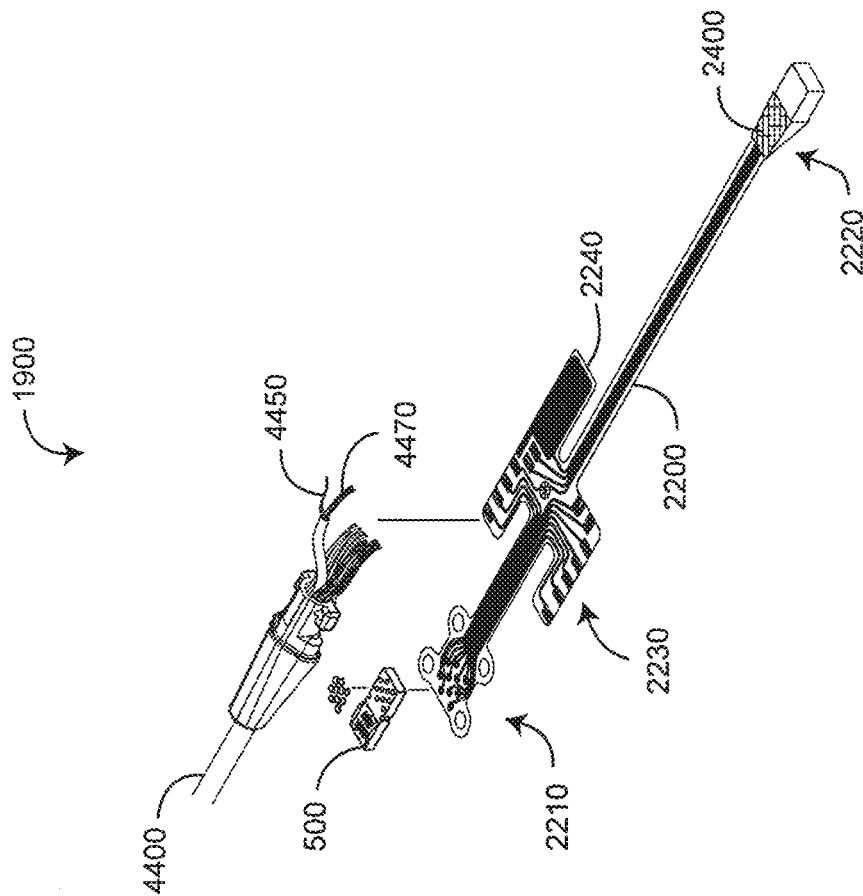


FIG. 21

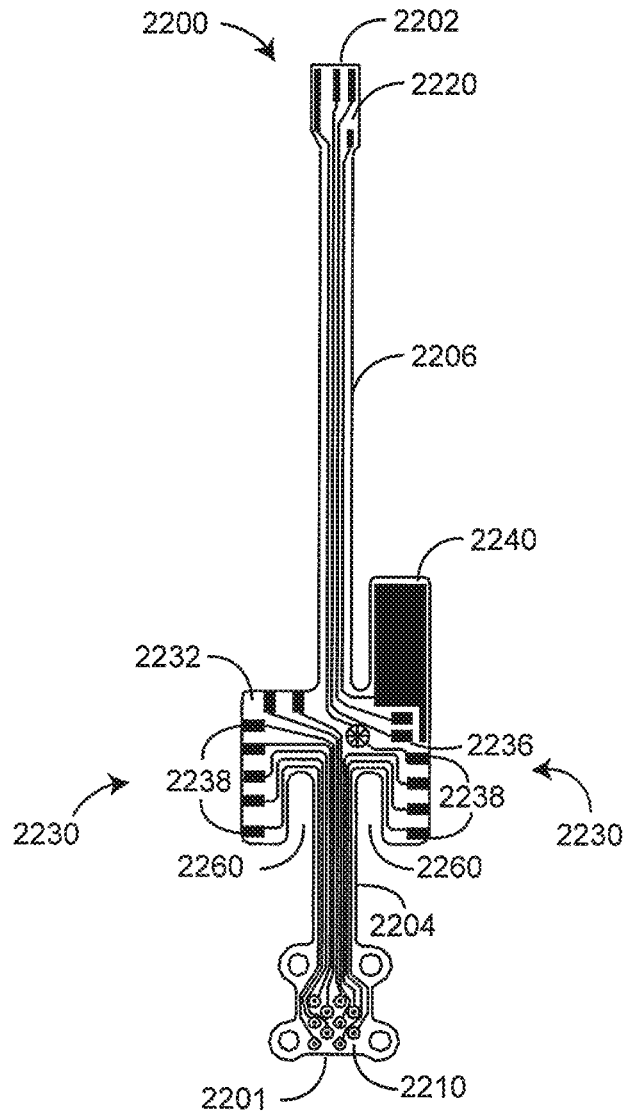


FIG. 22

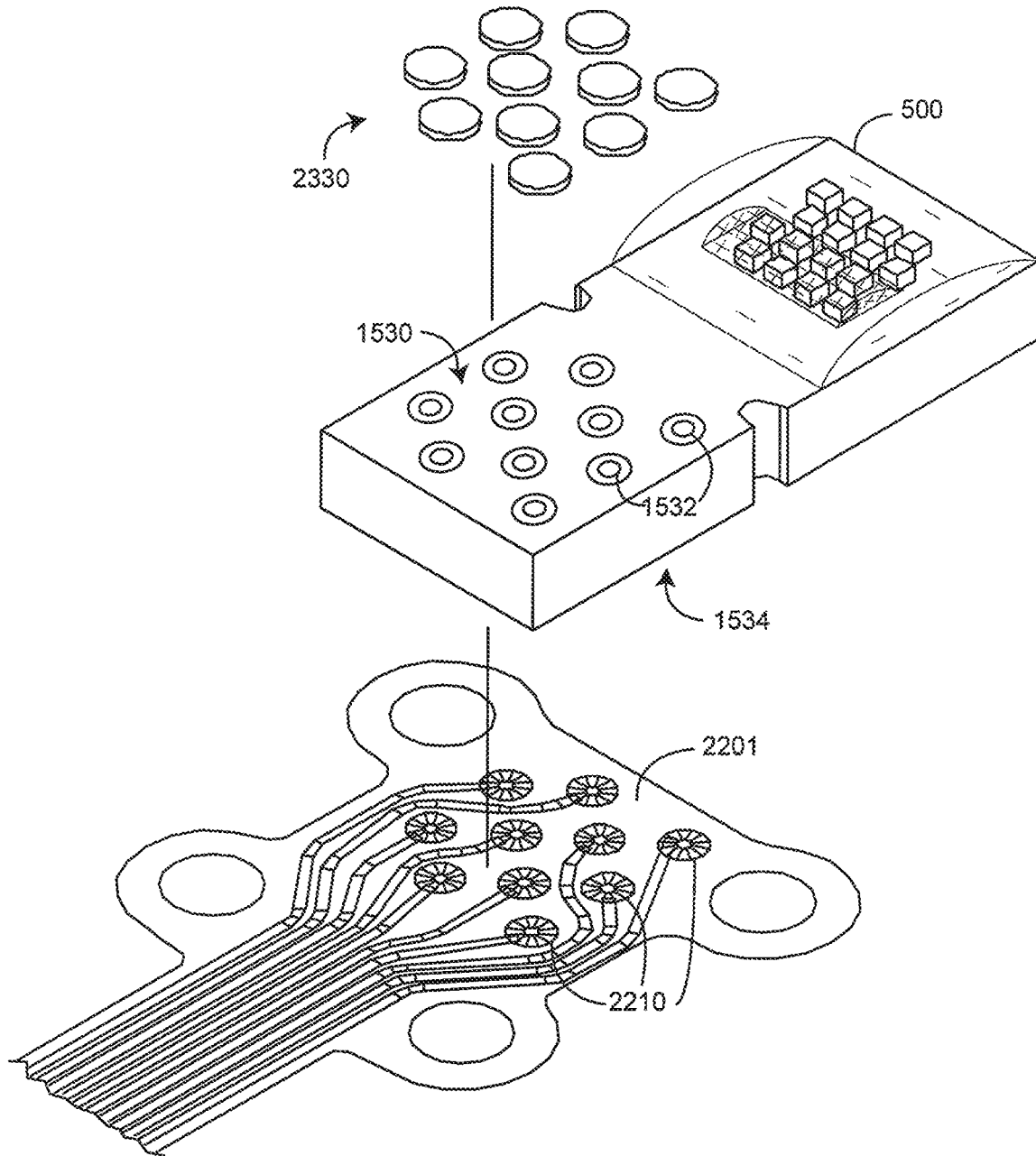


FIG. 23

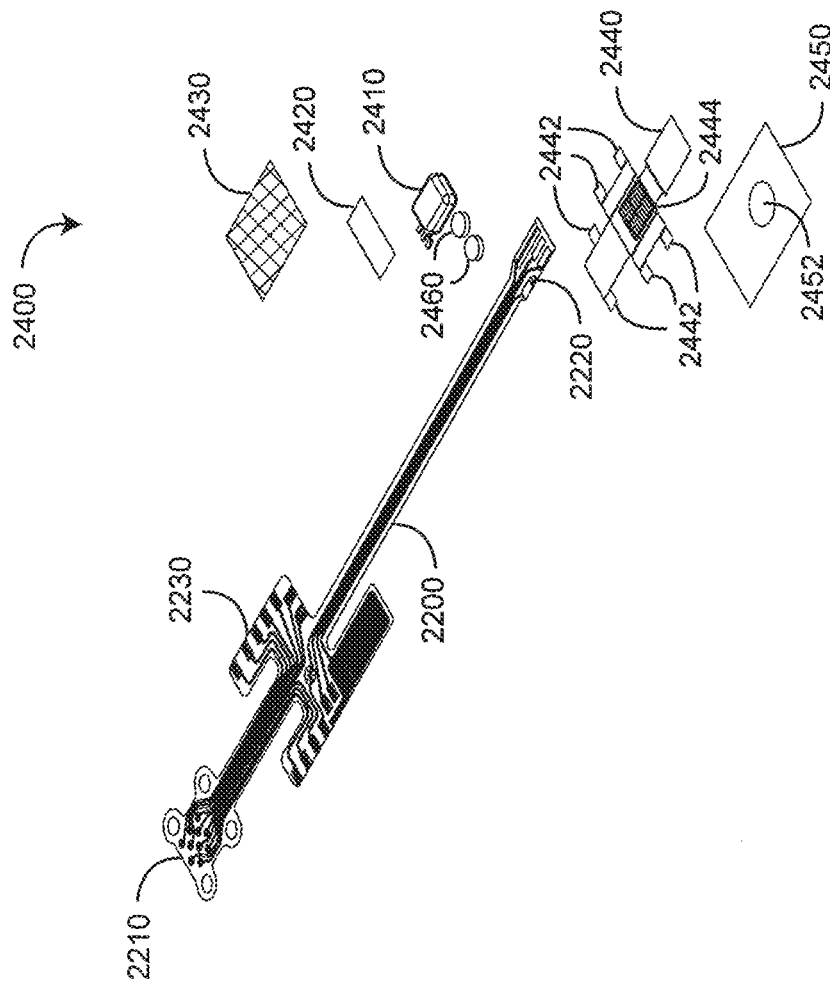


FIG. 24

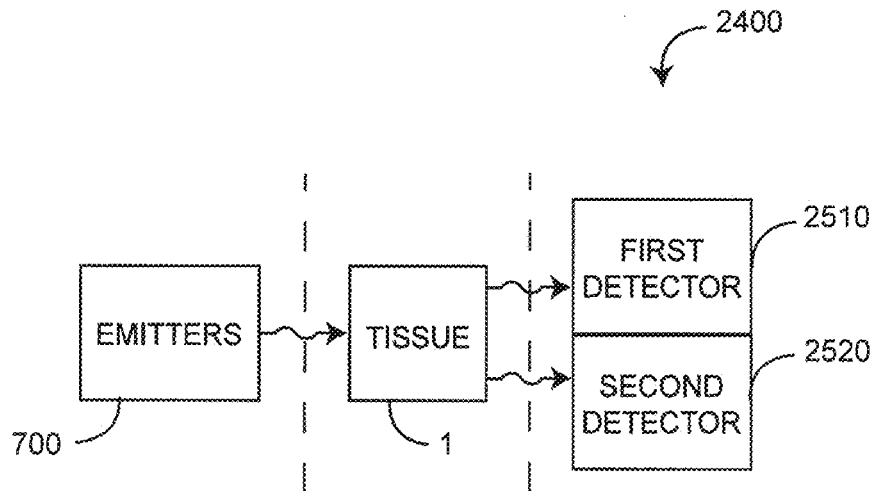


FIG. 25

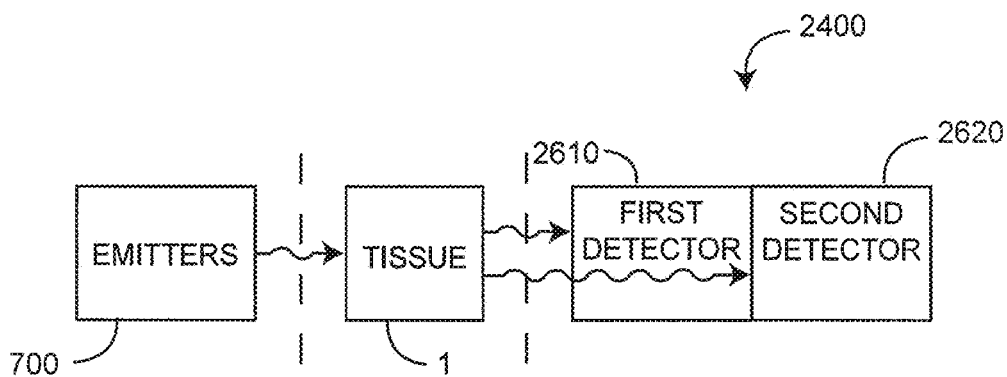


FIG. 26

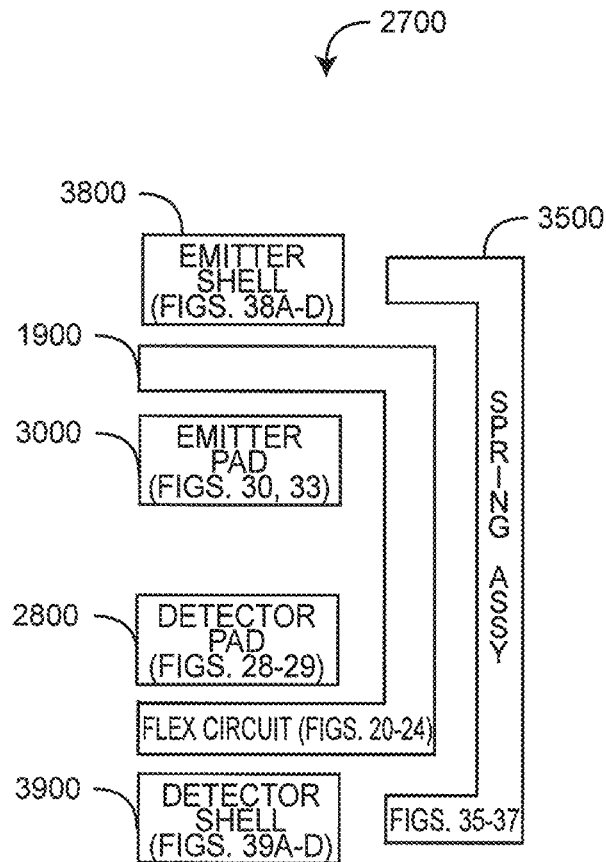


FIG. 27

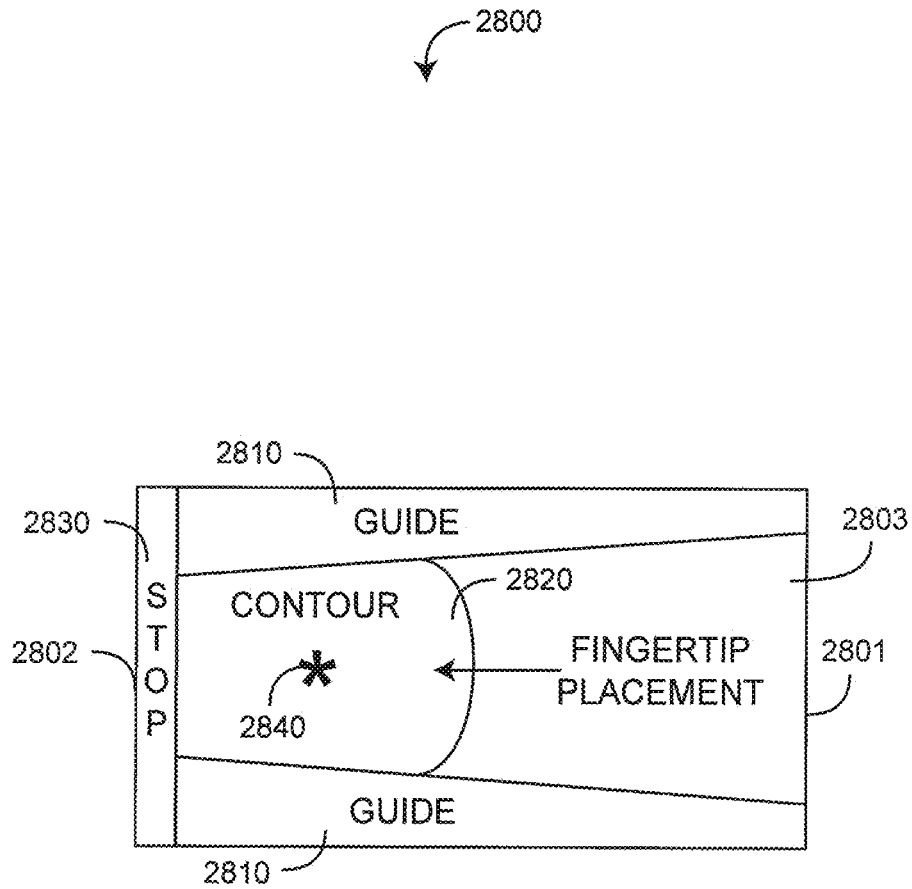


FIG. 28

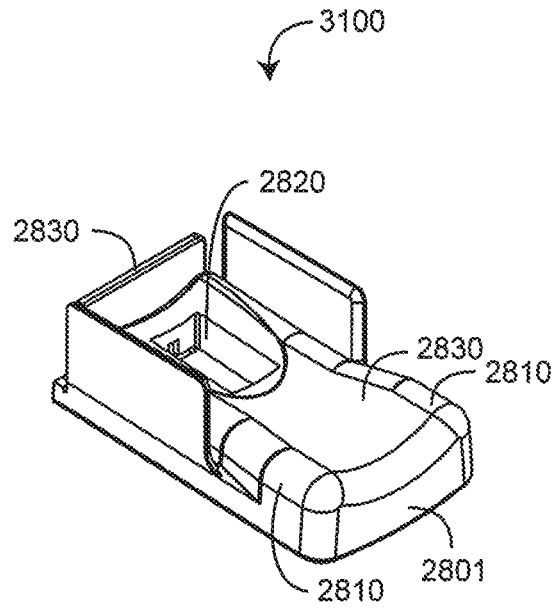


FIG. 29A

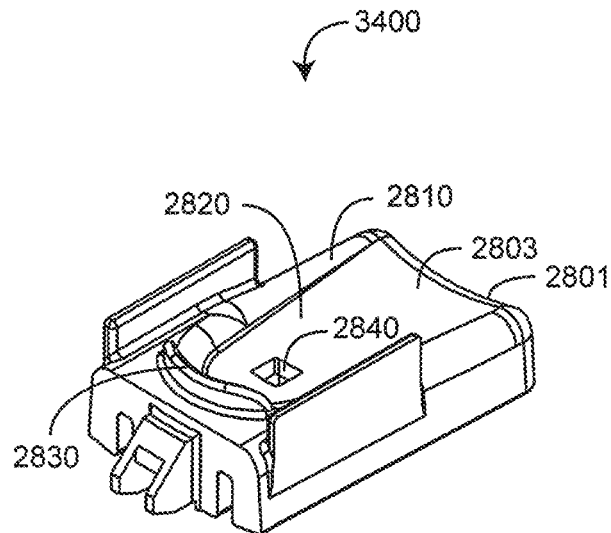


FIG. 29B

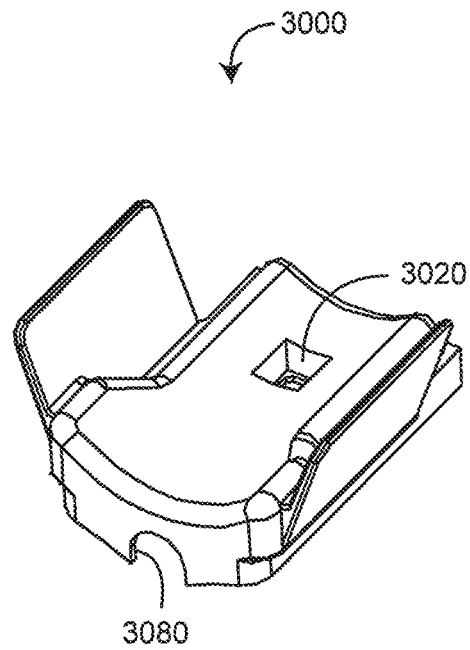


FIG. 30A

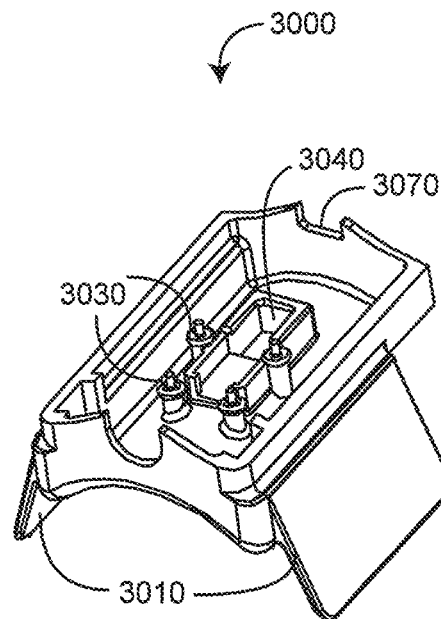


FIG. 30B

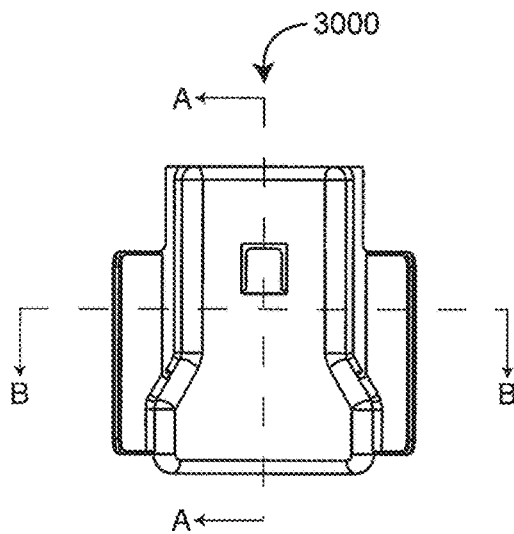


FIG. 30C

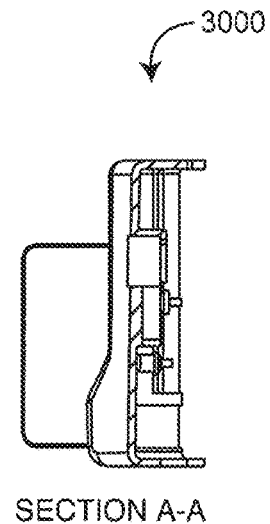


FIG. 30F

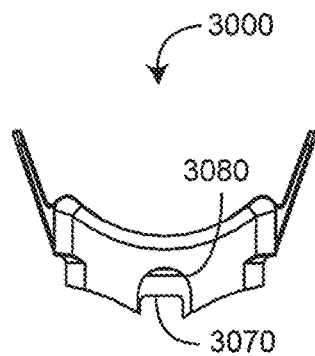


FIG. 30D

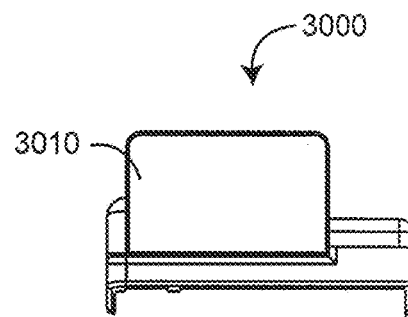


FIG. 30G

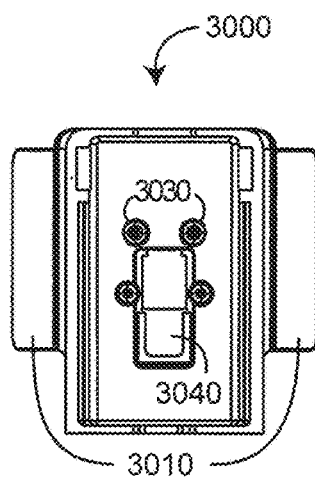


FIG. 30E

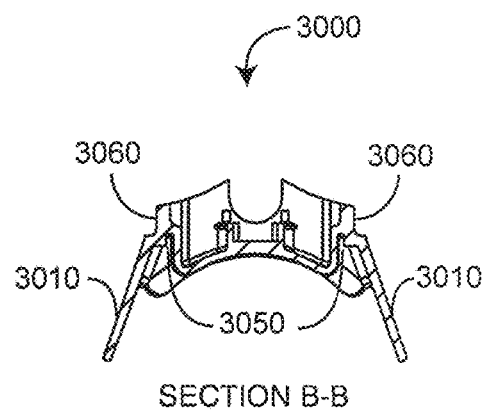


FIG. 30H

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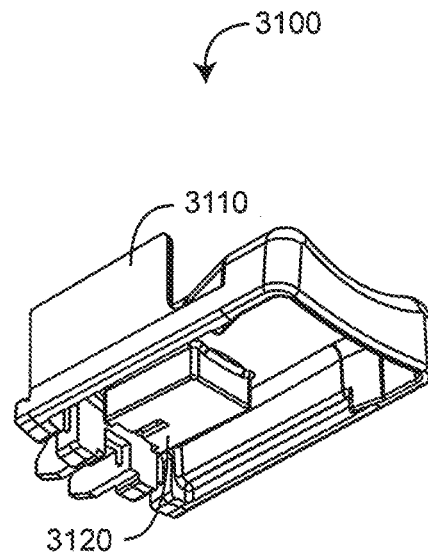


FIG. 31A

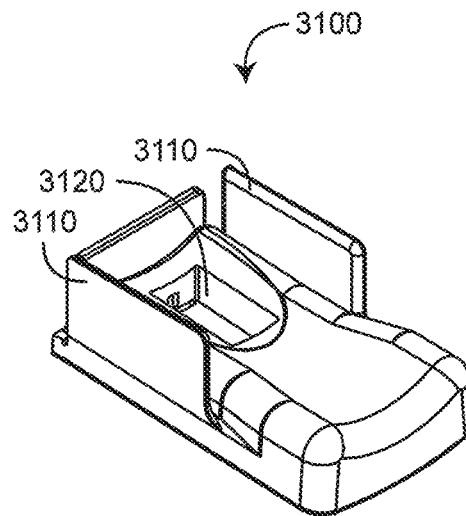


FIG. 31B

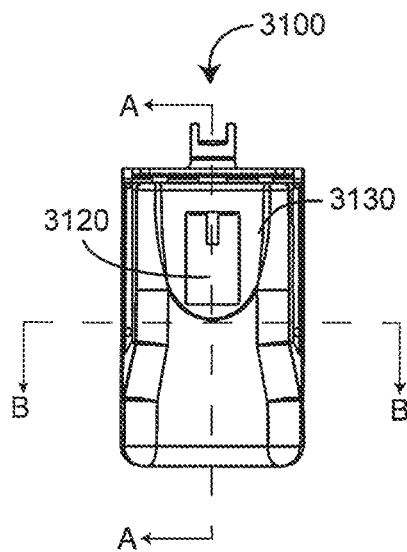
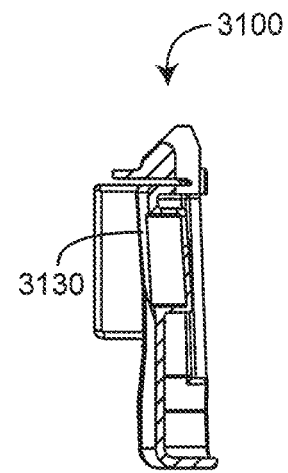


FIG. 31C



SECTION A-A

FIG. 31F

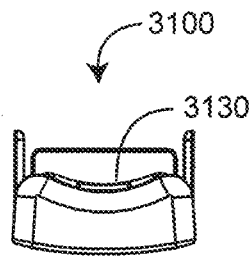


FIG. 31D

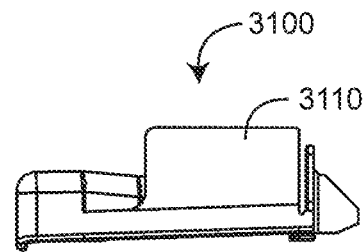


FIG. 31G

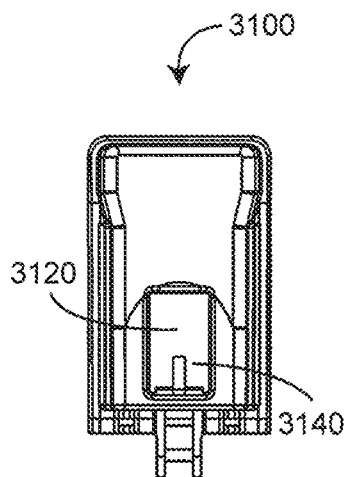
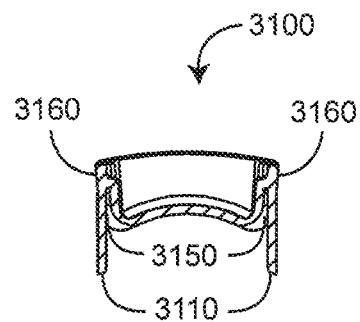


FIG. 31E



SECTION B-B

FIG. 31H

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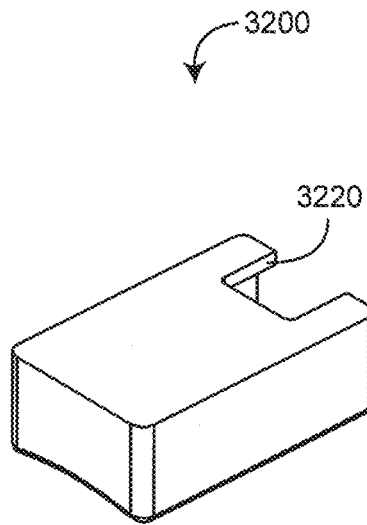


FIG. 32A

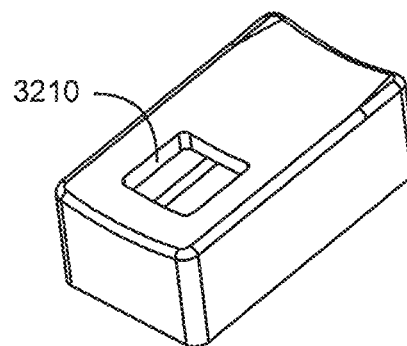


FIG. 32B

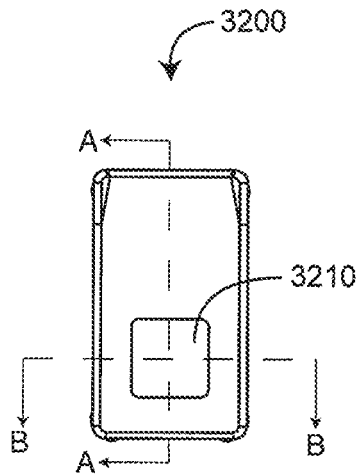
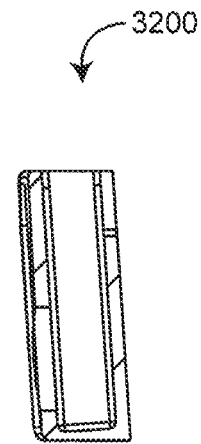


FIG. 32C



SECTION A-A

FIG. 32F

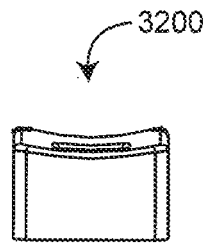


FIG. 32D

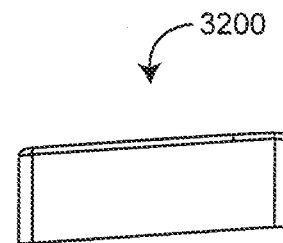


FIG. 32G

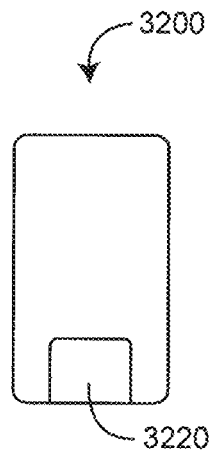
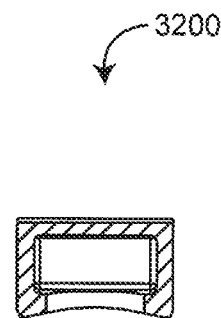


FIG. 32E



SECTION B-B

FIG. 32H

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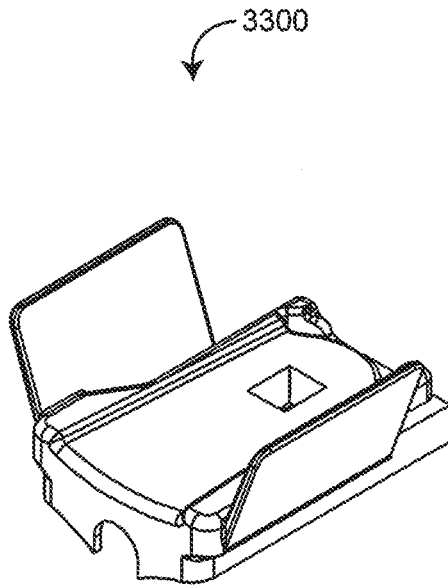


FIG. 33A

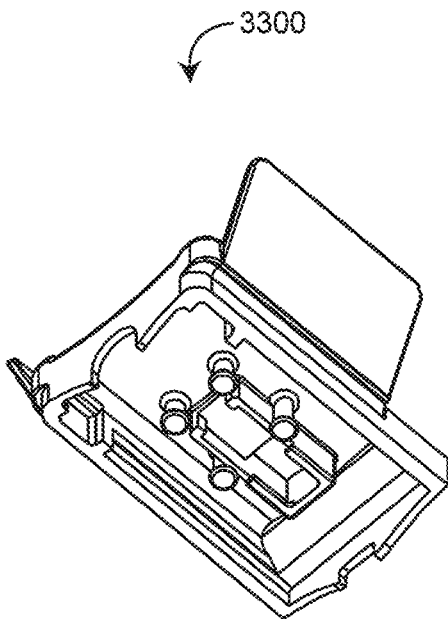


FIG. 33B

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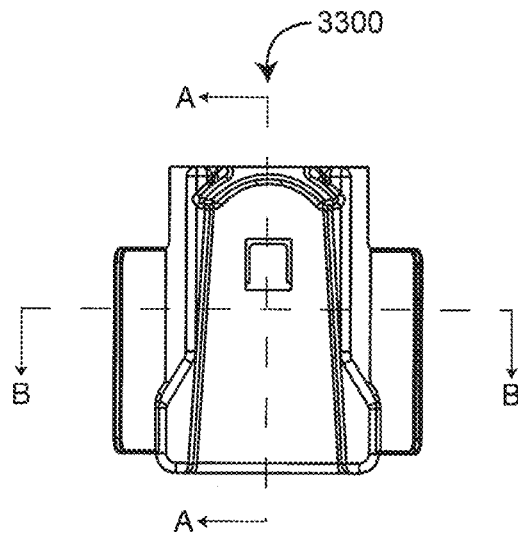


FIG. 33C

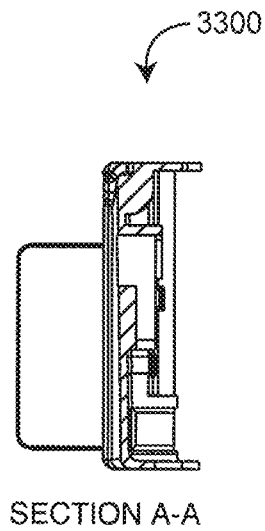


FIG. 33F

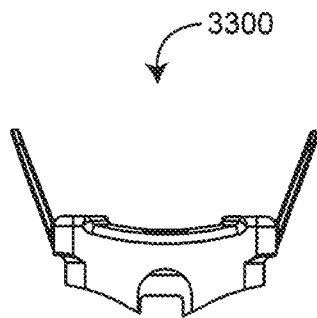


FIG. 33D

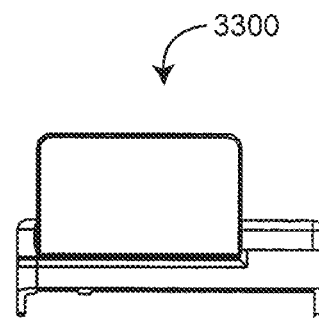


FIG. 33G

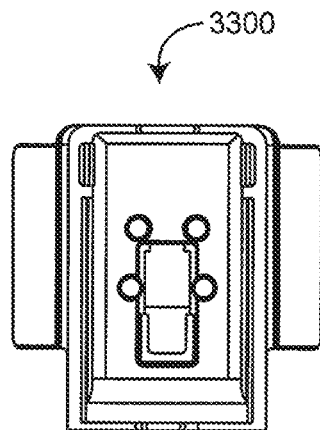


FIG. 33E

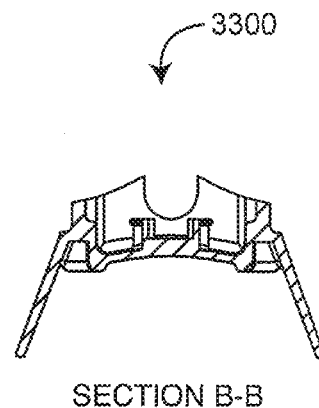


FIG. 33H

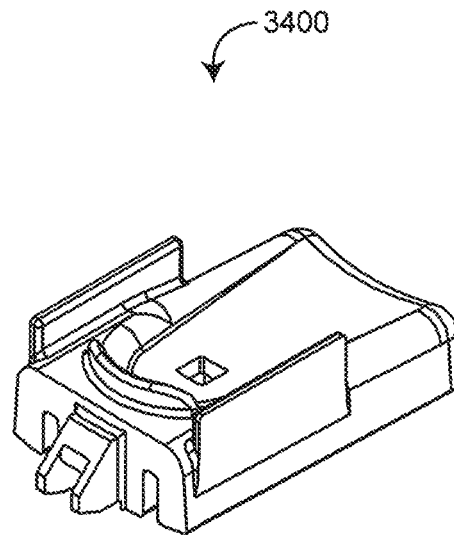


FIG. 34A

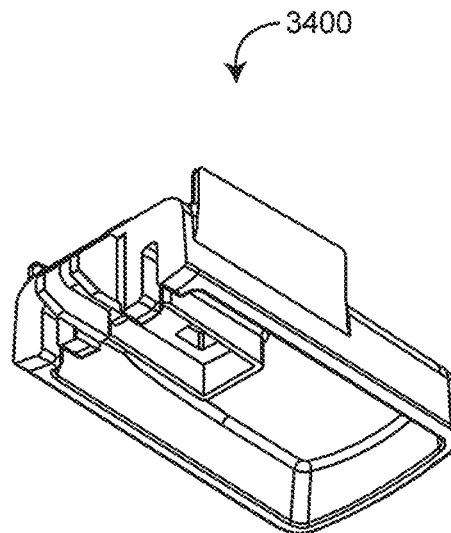


FIG. 34B

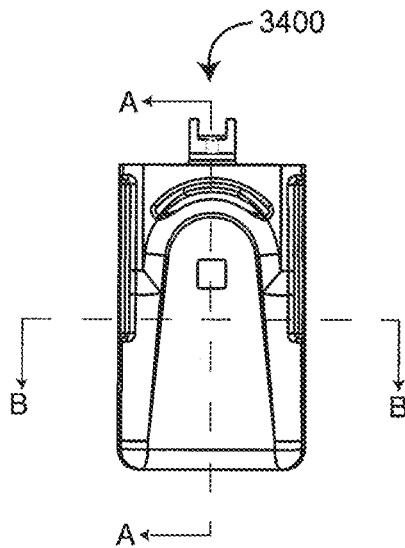


FIG. 34C

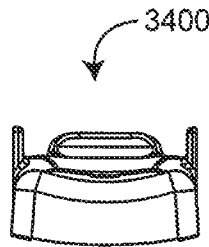


FIG. 34D

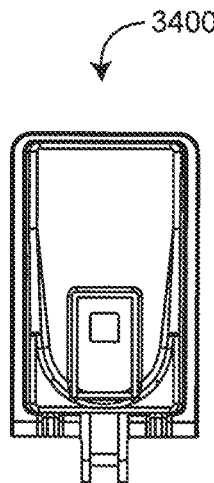
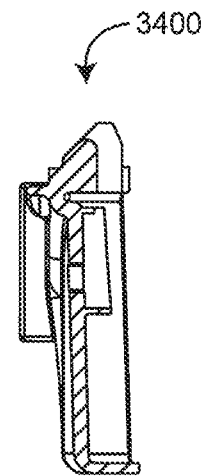


FIG. 34E



SECTION A-A

FIG. 34F

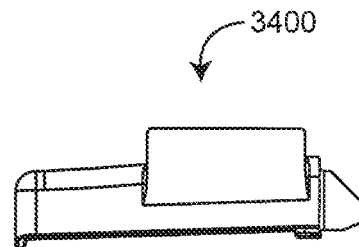
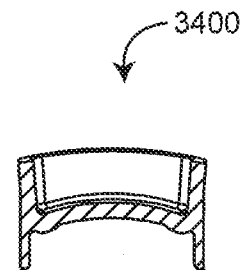


FIG. 34G



SECTION B-B

FIG. 34H

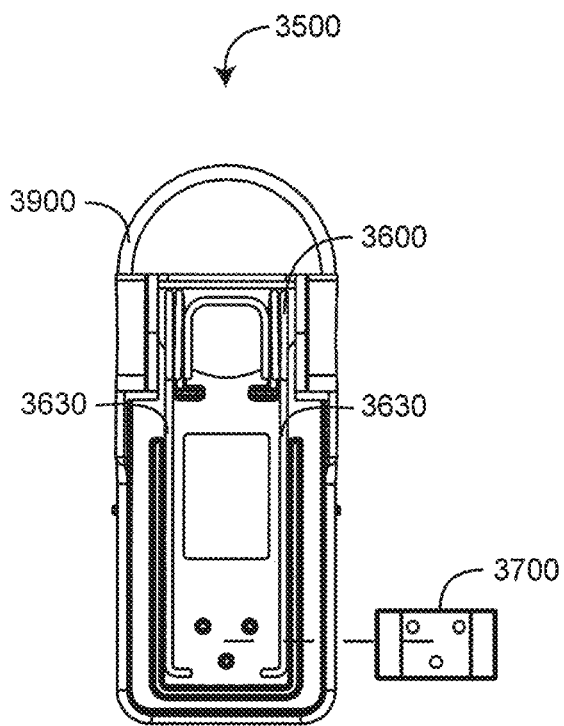


FIG. 35A

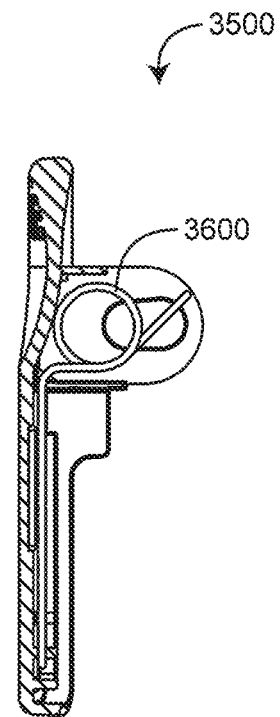


FIG. 35B

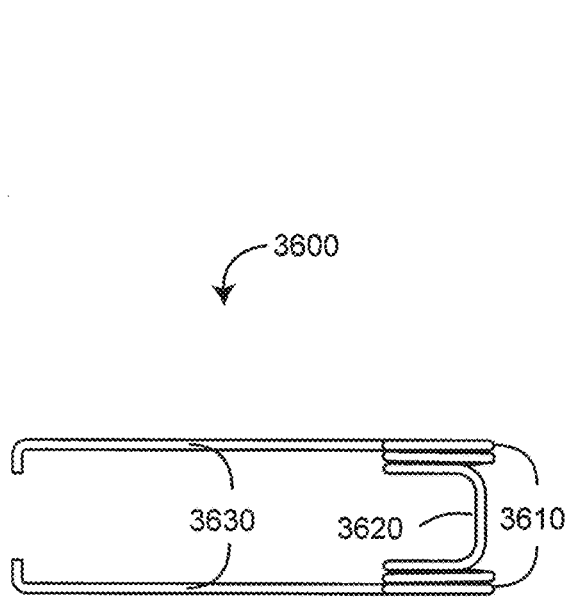


FIG. 36A

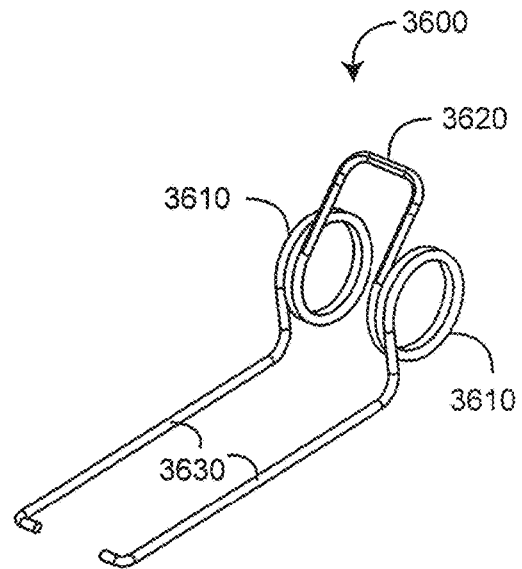


FIG. 36B

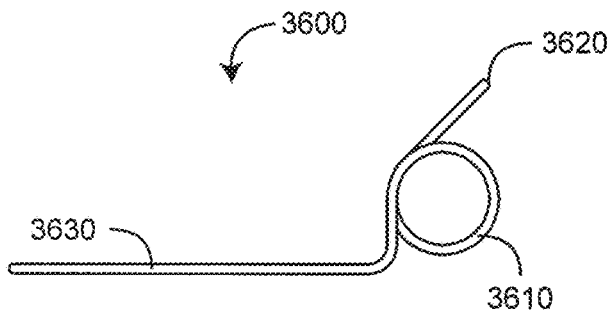


FIG. 36C

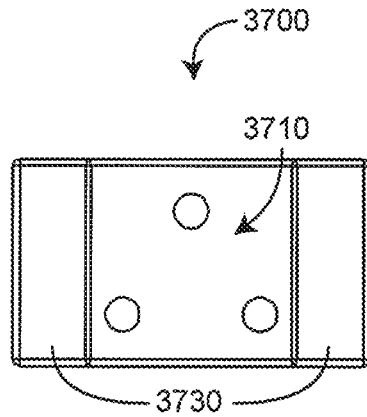


FIG. 37A

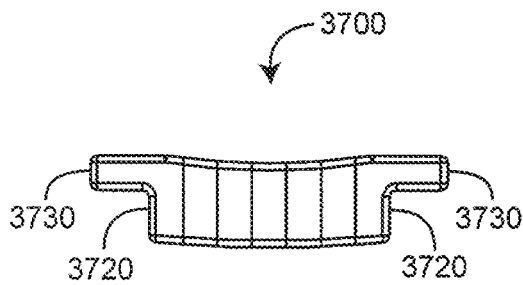


FIG. 37B

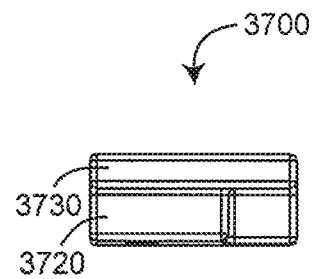


FIG. 37D

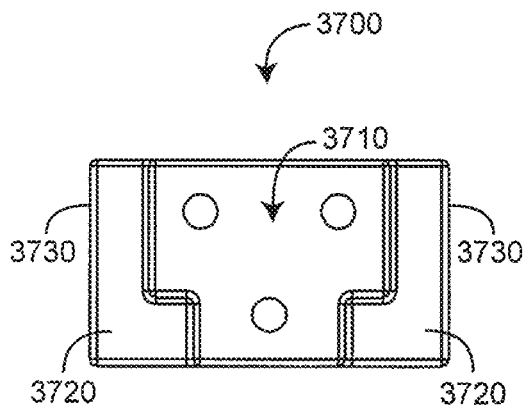


FIG. 37C

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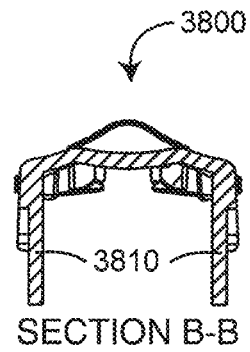


FIG. 38A

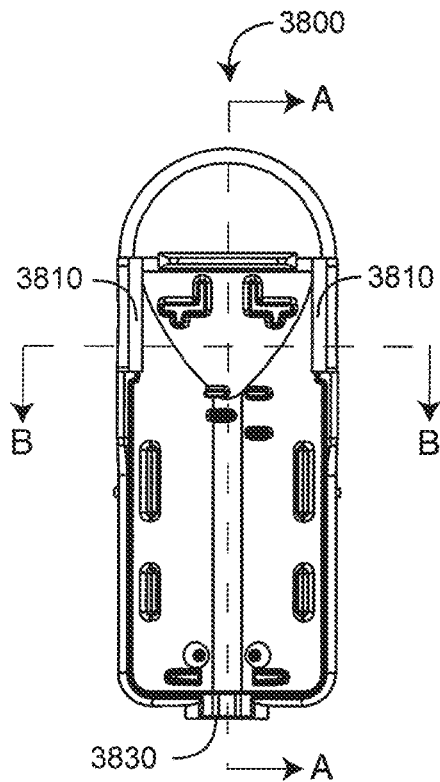


FIG. 38B

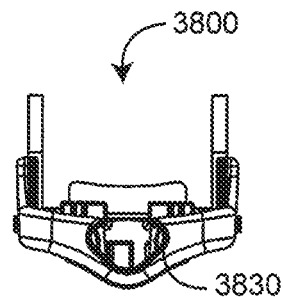
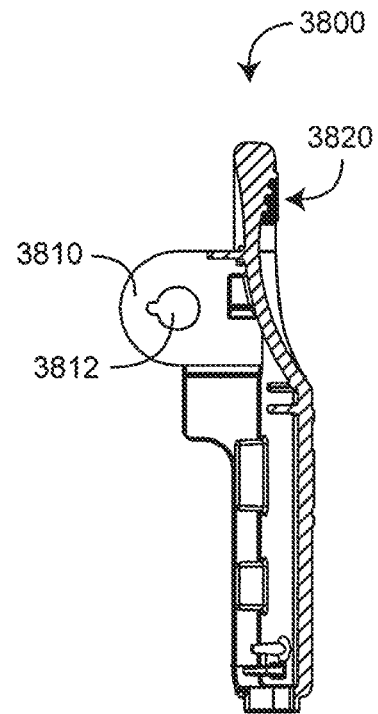


FIG. 38C



SECTION A-A
FIG. 38D

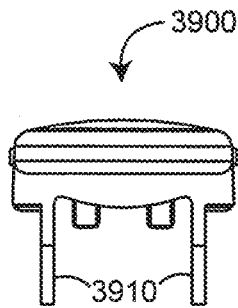


FIG. 39A

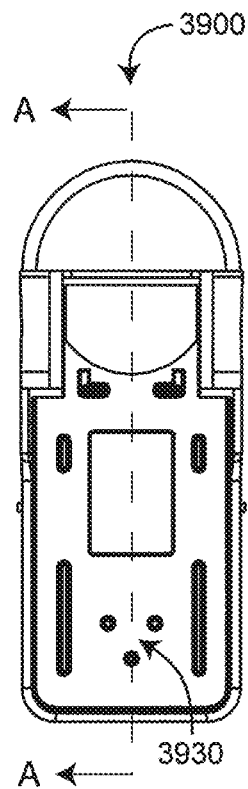


FIG. 39B

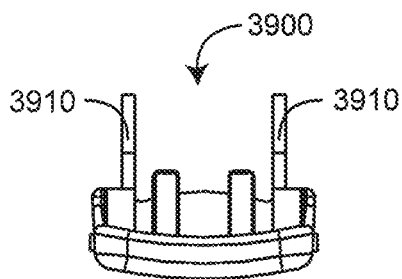
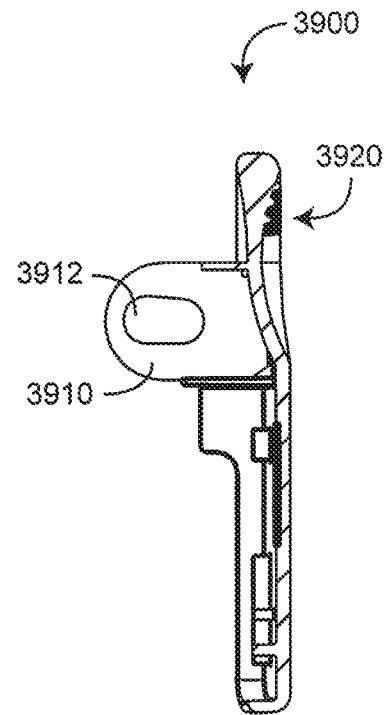


FIG. 39C



SECTION A-A
FIG. 39D

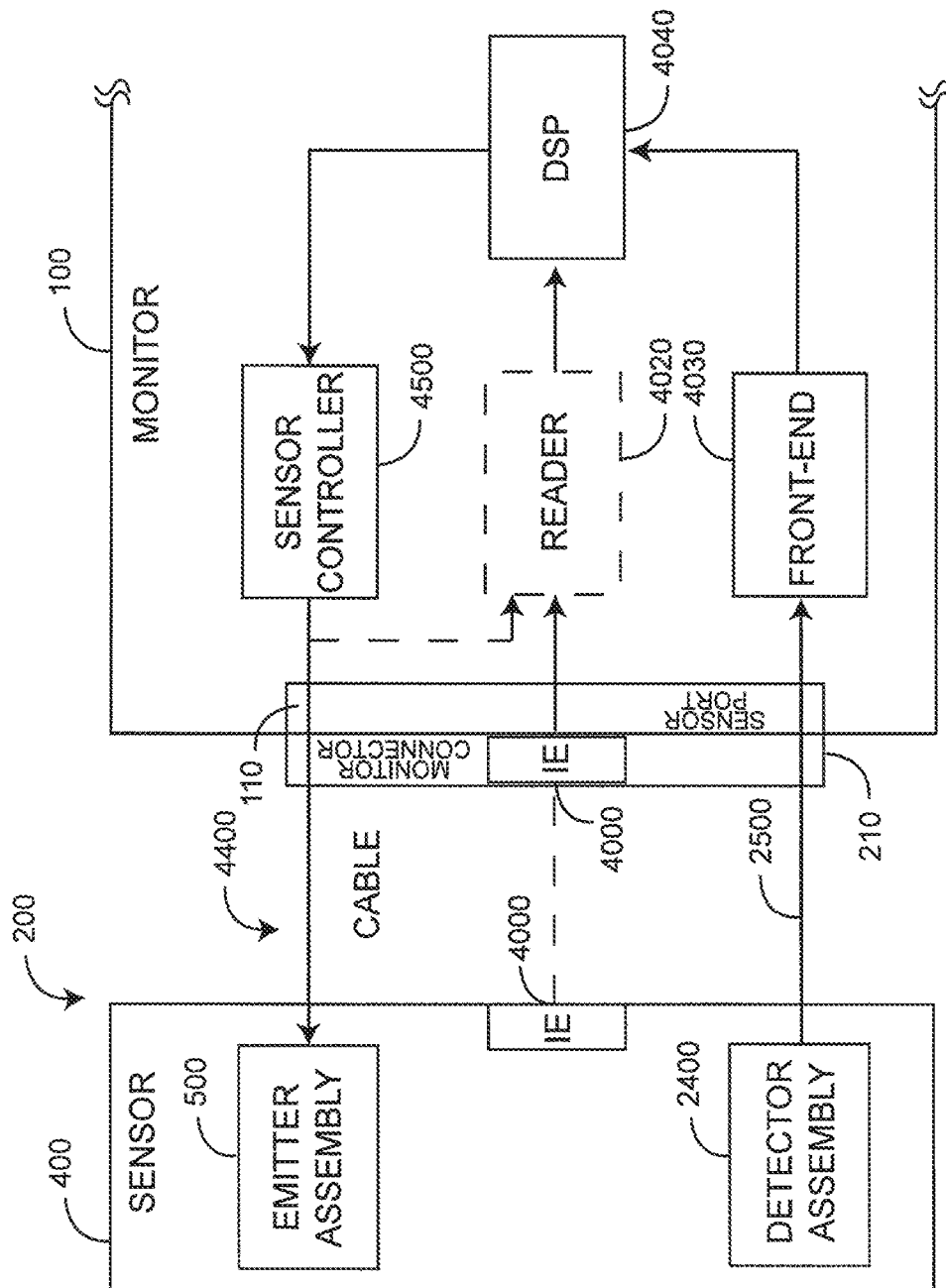
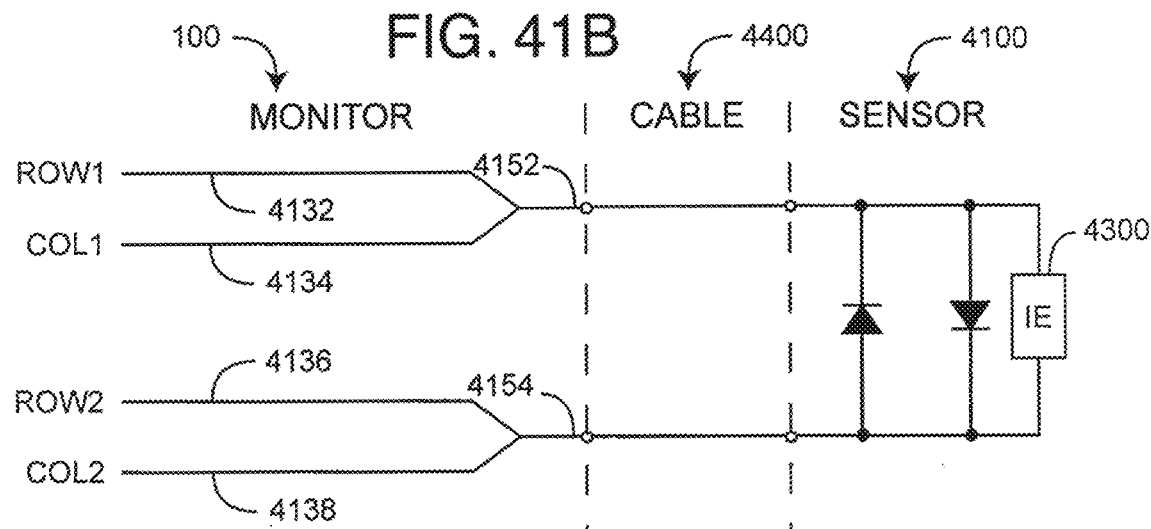
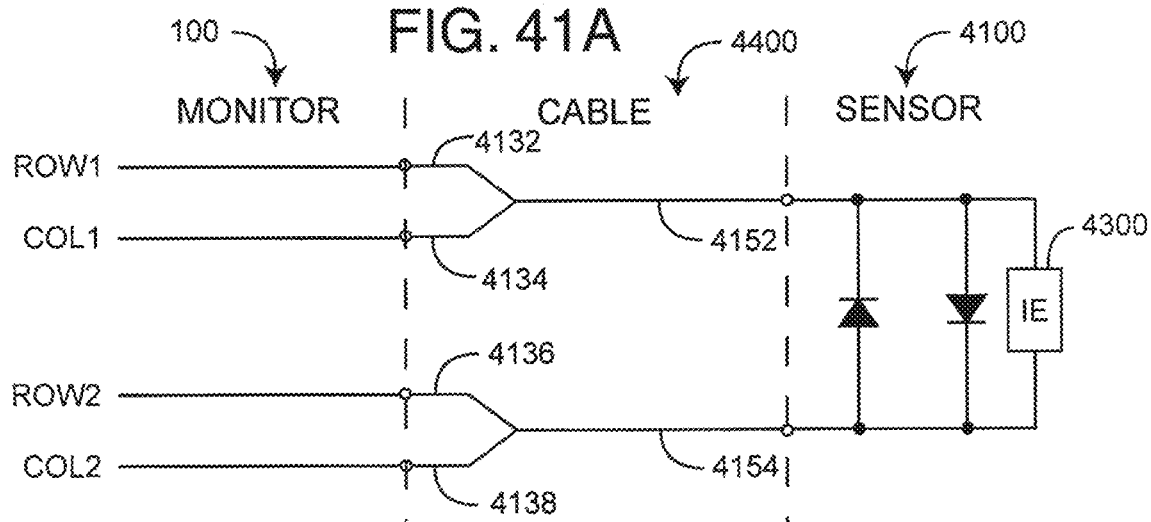
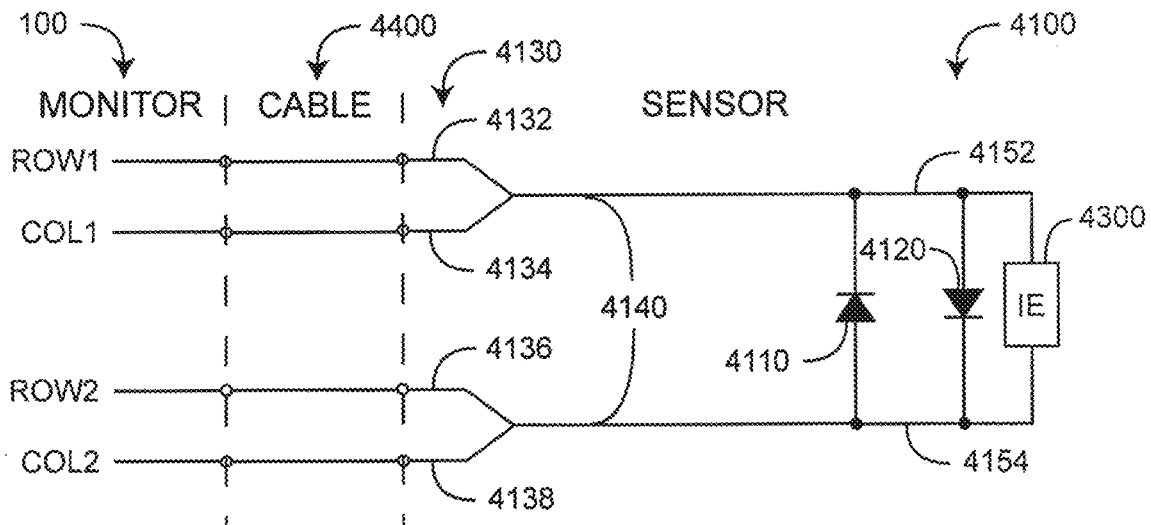


FIG. 40



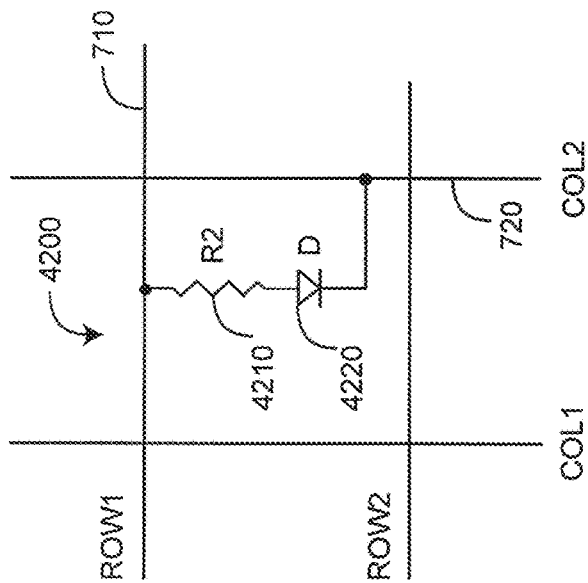


FIG. 42

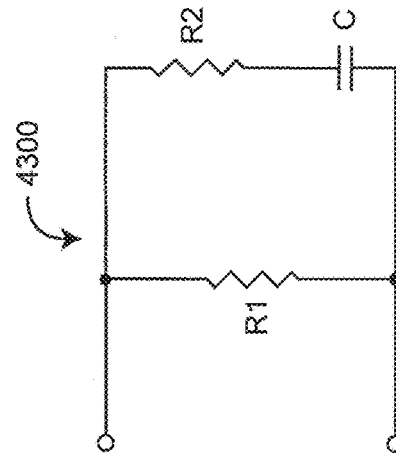


FIG. 43A

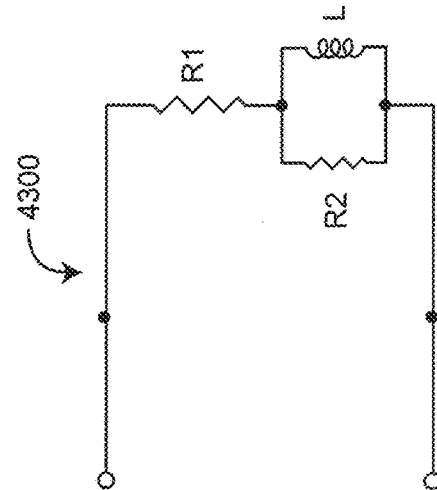


FIG. 43B

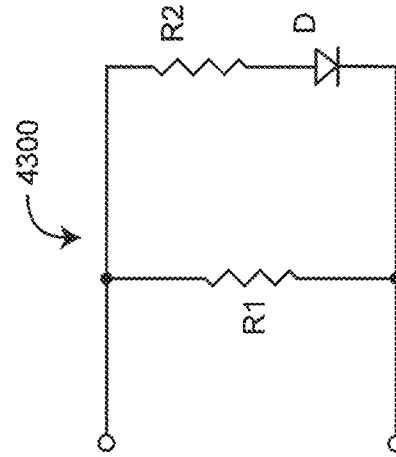


FIG. 43C

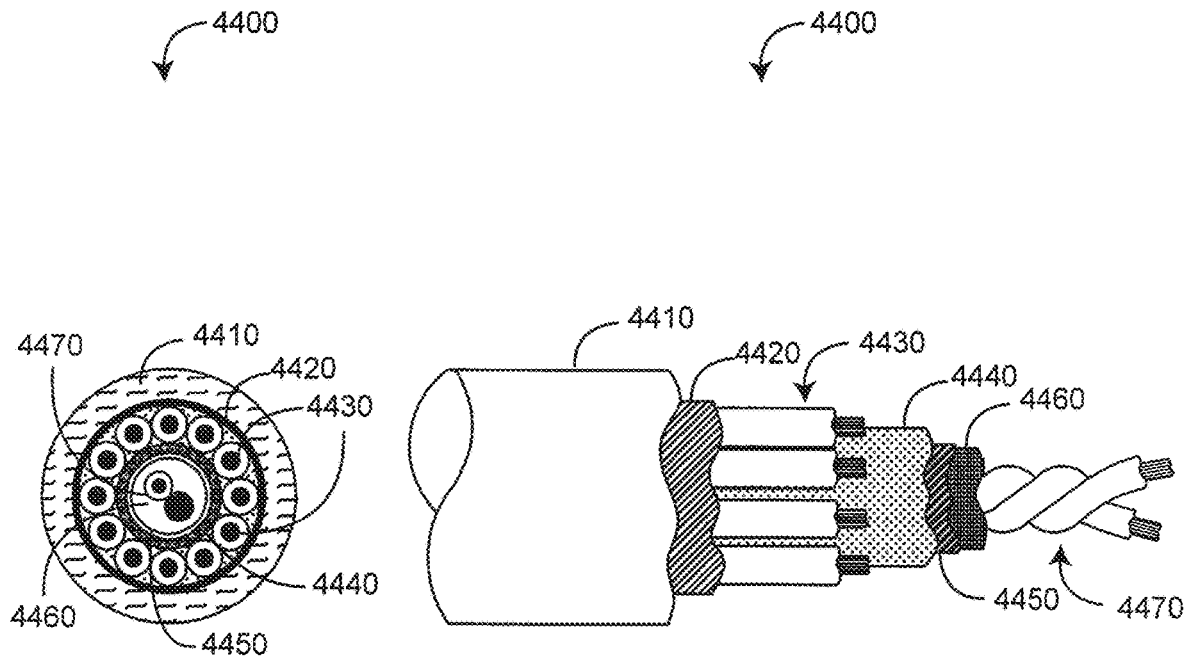


FIG. 44A

FIG. 44B

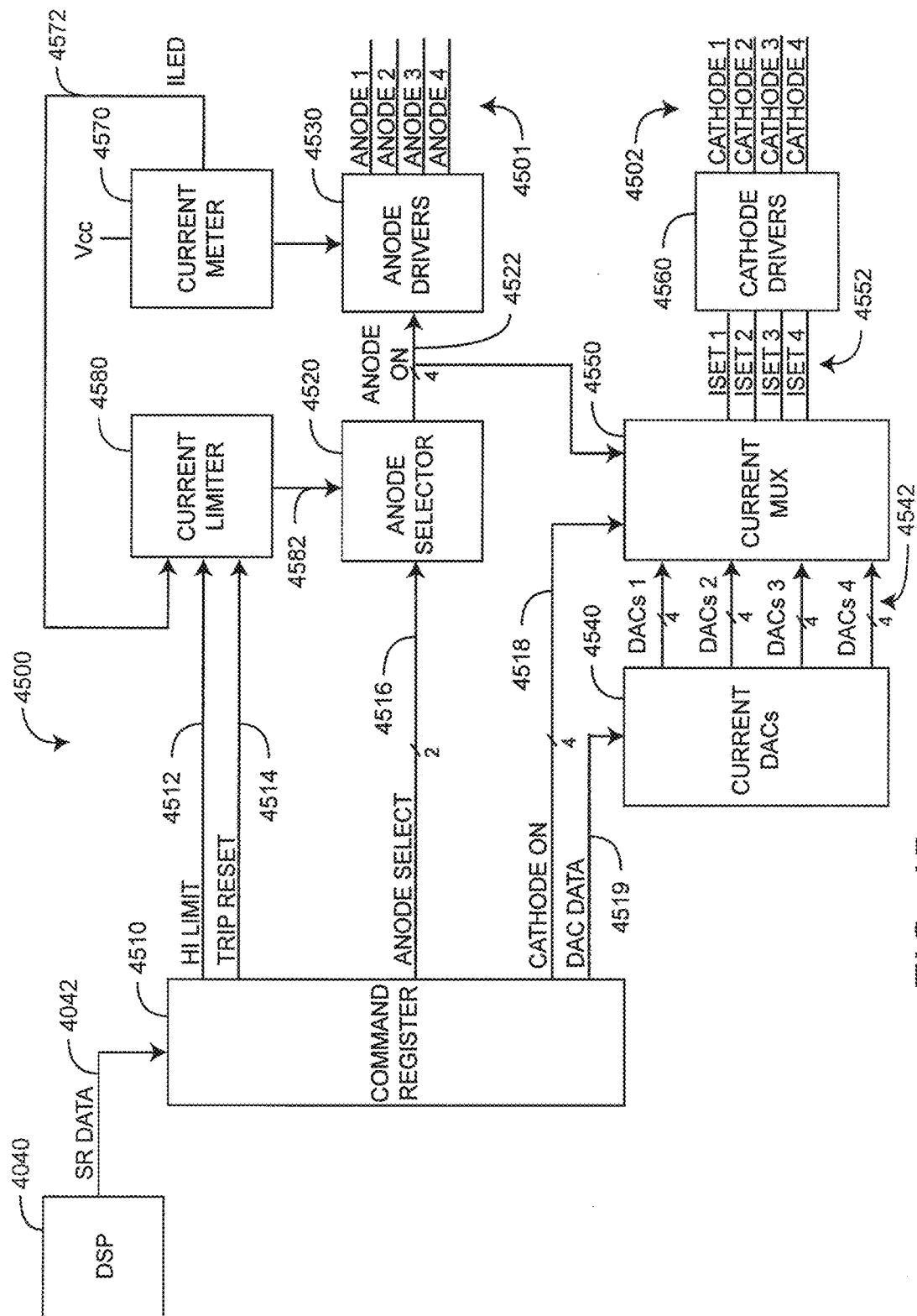


FIG. 45

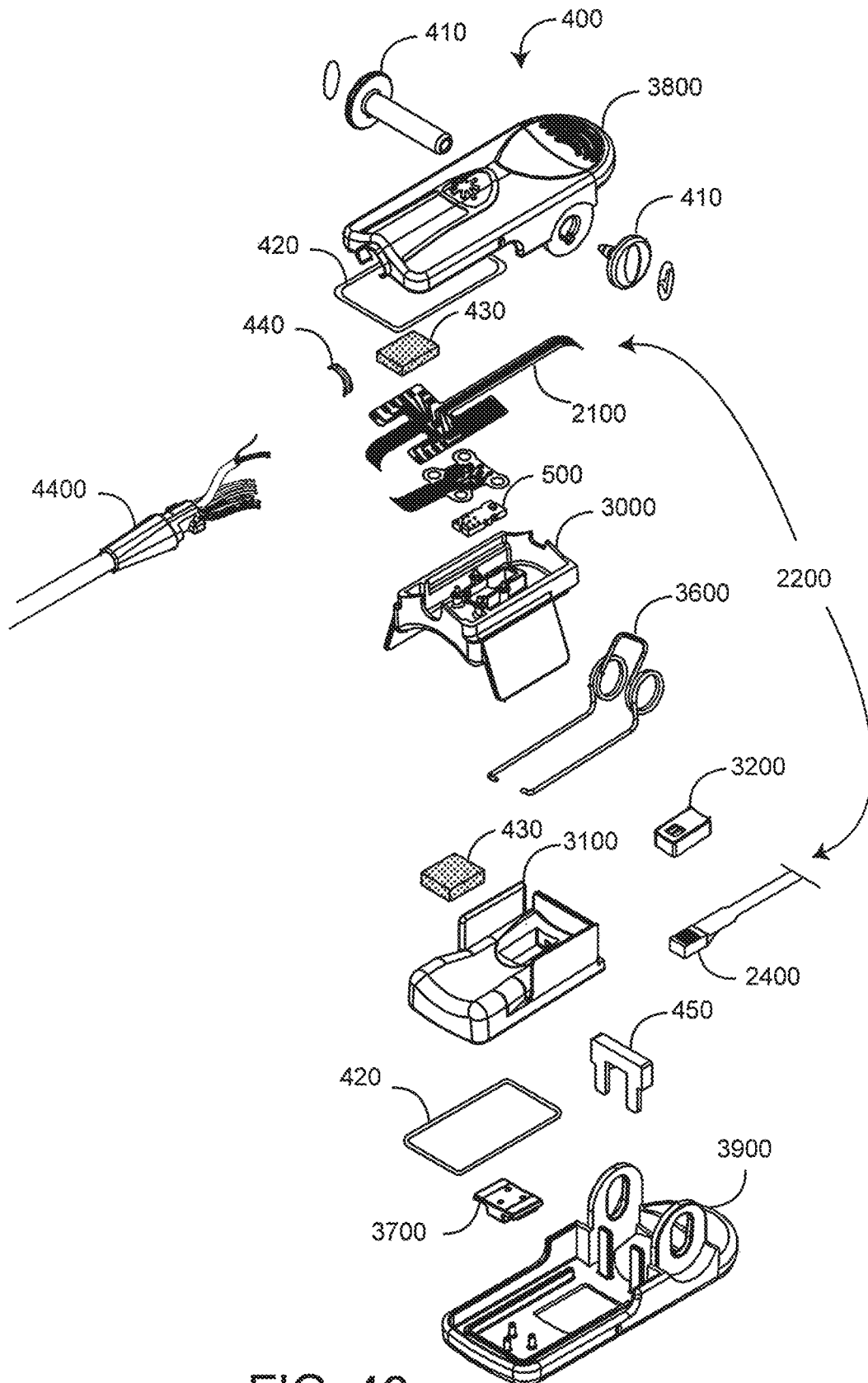


FIG. 46

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**MULTIPLE WAVELENGTH SENSOR
EMITTERS****PRIORITY CLAIM**

The present application is a continuation of U.S. patent application Ser. No. 16/437,611, entitled "Multiple Wavelength Sensor Emitters," filed Jun. 11, 2019, which is a continuation of U.S. patent application Ser. No. 15/694,541, entitled "Multiple Wavelength Sensor Emitters," filed Sep. 1, 2017, now issued as U.S. Pat. No. 10,327,683, which is a continuation of U.S. patent application Ser. No. 14/472,760, entitled "Multiple Wavelength Sensor Emitters," filed Aug. 29, 2014, now issued as U.S. Pat. No. 9,750,443, which is a continuation of U.S. patent application Ser. No. 13/776,065, entitled "Multiple Wavelength Sensor Emitters," filed Feb. 25, 2013, now issued as U.S. Pat. No. 8,849,365, which is a continuation of U.S. patent application Ser. No. 12/422,915, entitled "Multiple Wavelength Sensor Emitters," filed Apr. 13, 2009, now issued as U.S. Pat. No. 8,385,996, which is a continuation of U.S. patent application Ser. No. 11/367,013, entitled "Multiple Wavelength Sensor Emitters," filed Mar. 1, 2006, now issued as U.S. Pat. No. 7,764,982, which claims priority benefit to U.S. Provisional Patent App. No. 60/657,596, filed Mar. 1, 2005, entitled "Multiple Wavelength Sensor," U.S. Provisional Patent App. No. 60/657,281, filed Mar. 1, 2005, entitled "Physiological Parameter Confidence Measure," U.S. Provisional Patent App. No. 60/657,268, filed Mar. 1, 2005, entitled "Configurable Physiological Measurement System," and U.S. Provisional Patent App. No. 60/657,759, filed Mar. 1, 2005, entitled "Noninvasive Multi-Parameter Patient Monitor." The present application incorporates each of the foregoing disclosures herein by reference in its entirety and for all purposes.

**INCORPORATION BY REFERENCE OF
RELATED APPLICATIONS**

The present application is related to the following U.S. utility applications:

	App. Ser. No.	Filing Date	Title	Atty Dock.
1	11/367,013	Mar. 1, 2006	Multiple Wavelength Sensor Emitters	MLR.002A
	11/546,932	Oct. 12, 2006	Disposable Wavelength Optical Sensor	MLR.002CP1
2	11/366,995	Mar. 1, 2006	Multiple Wavelength Sensor Equalization	MLR.003A
3	11/366,209	Mar. 1, 2006	Multiple Wavelength Sensor Substrate	MLR.004A
4	11/366,210	Mar. 1, 2006	Multiple Wavelength Sensor Interconnect	MLR.005A
5	11/366,833	Mar. 1, 2006	Multiple Wavelength Sensor Attachment	MLR.006A
6	11/366,997	Mar. 1, 2006	Multiple Wavelength Sensor Drivers	MLR.009A
7	11/367,034	Mar. 1, 2006	Physiological Parameter Confidence Measure	MLR.010A
8	11/367,036	Mar. 1, 2006	Configurable Physiological Measurement System	MLR.011A
9	11/367,033	Mar. 1, 2006	Noninvasive Multi-Parameter Patient Monitor	MLR.012A
10	11/367,014	Mar. 1, 2006	Noninvasive Multi-Parameter Patient Monitor	MLR.013A
11	11/366,208	Mar. 1, 2006	Noninvasive Multi-Parameter Patient Monitor	MLR.014A
12	12/056,179	Mar. 26, 2008	Multiple Wavelength Optical Sensor	MLR.015A
13	12/082,810	Apr. 14, 2008	Optical Sensor Assembly	MLR.015A2

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The present application incorporates the foregoing disclosures herein by reference.

BACKGROUND

Spectroscopy is a common technique for measuring the concentration of organic and some inorganic constituents of a solution. The theoretical basis of this technique is the Beer-Lambert law, which states that the concentration c , of an absorbent in solution can be determined by the intensity of light transmitted through the solution, knowing the path-length d_λ , the intensity of the incident light $I_{0,\lambda}$, and the extinction coefficient $\epsilon_{i,\lambda}$ at a particular wavelength λ . In generalized form, the Beer-Lambert law is expressed as:

$$I_\lambda = I_{0,\lambda} e^{-d_\lambda \mu_{a,\lambda}} \quad (1)$$

$$\mu_{a,\lambda} = \sum_{i=1}^n \epsilon_{i,\lambda} \cdot c_i \quad (2)$$

where, $\mu_{a,\lambda}$ is the bulk absorption coefficient and represents the probability of absorption per unit length. The minimum number of discrete wavelengths that are required to solve EQS. 1-2 are the number of significant absorbers that are present in the solution.

A practical application of this technique is pulse oximetry, which utilizes a noninvasive sensor to measure oxygen saturation (SpO_2) and pulse rate. In general, the sensor has light emitting diodes (LEDs) that transmit optical radiation of red and infrared wavelengths into a tissue site and a detector that responds to the intensity of the optical radiation after absorption (e.g., by transmission or transreflectance) by pulsatile arterial blood flowing within the tissue site. Based on this response, a processor determines measurements for SpO_2 , pulse rate, and can output representative plethysmographic waveforms. Thus, "pulse oximetry" as used herein encompasses its broad ordinary meaning known to one of skill in the art, which includes at least those noninvasive

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procedures for measuring parameters of circulating blood through spectroscopy. Moreover, "plethysmograph" as used herein (commonly referred to as "photoplethysmograph"), encompasses its broad ordinary meaning known to one of skill in the art, which includes at least data representative of a change in the absorption of particular wavelengths of light as a function of the changes in body tissue resulting from pulsing blood. Pulse oximeters capable of reading through motion induced noise are available from Masimo Corporation ("Masimo") of Irvine, Calif. Moreover, portable and other oximeters capable of reading through motion induced noise are disclosed in at least U.S. Pat. Nos. 6,770,028, 6,658,276, 6,157,850, 6,002,952, 5,769,785, and 5,758,644, which are owned by Masimo and are incorporated by reference herein. Such reading through motion oximeters have gained rapid acceptance in a wide variety of medical applications, including surgical wards, intensive care and neonatal units, general wards, home care, physical training, and virtually all types of monitoring scenarios.

SUMMARY

There is a need to noninvasively measure multiple physiological parameters, other than, or in addition to, oxygen saturation and pulse rate. For example, hemoglobin species that are also significant under certain circumstances are carboxyhemoglobin and methemoglobin. Other blood parameters that may be measured to provide important clinical information are fractional oxygen saturation, total hemoglobin (Hbt), bilirubin and blood glucose, to name a few.

One aspect of a physiological sensor is light emitting sources, each activated by addressing at least one row and at least one column of an electrical grid. The light emitting sources transmit light having multiple wavelengths and a detector is responsive to the transmitted light after attenuation by body tissue.

Another aspect of a physiological sensor is light emitting sources capable of transmitting light having multiple wavelengths. Each of the light emitting sources includes a first contact and a second contact. The first contacts of a first set of the light emitting sources are in communication with a first conductor and the second contacts of a second set of the light emitting sources are in communication with a second conductor. A detector is capable of detecting the transmitted light attenuated by body tissue and outputting a signal indicative of at least one physiological parameter of the body tissue. At least one light emitting source of the first set and at least one light emitting source of the second set are not common to the first and second sets. Further, each of the first set and the second set comprises at least two of the light emitting sources.

A further aspect of a physiological sensor sequentially addresses light emitting sources using conductors of an electrical grid so as to emit light having multiple wavelengths that when attenuated by body tissue is indicative of at least one physiological characteristic. The emitted light is detected after attenuation by body tissue.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of a physiological measurement system utilizing a multiple wavelength sensor;

FIGS. 2A-C are perspective views of multiple wavelength sensor embodiments;

FIG. 3 is a general block diagram of a multiple wavelength sensor and sensor controller;

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FIG. 4 is an exploded perspective view of a multiple wavelength sensor embodiment;

FIG. 5 is a general block diagram of an emitter assembly;

FIG. 6 is a perspective view of an emitter assembly embodiment;

FIG. 7 is a general block diagram of an emitter array;

FIG. 8 is a schematic diagram of an emitter array embodiment;

FIG. 9 is a general block diagram of equalization;

FIGS. 10A-D are block diagrams of various equalization embodiments;

FIGS. 11A-C are perspective views of an emitter assembly incorporating various equalization embodiments;

FIG. 12 is a general block diagram of an emitter substrate;

FIGS. 13-14 are top and detailed side views of an emitter substrate embodiment;

FIG. 15-16 are top and bottom component layout views of an emitter substrate embodiment;

FIG. 17 is a schematic diagram of an emitter substrate embodiment;

FIG. 18 is a plan view of an inner layer of an emitter substrate embodiment;

FIG. 19 is a general block diagram of an interconnect assembly in relationship to other sensor assemblies;

FIG. 20 is a block diagram of an interconnect assembly embodiment;

FIG. 21 is a partially-exploded perspective view of a flex circuit assembly embodiment of an interconnect assembly;

FIG. 22 is a top plan view of a flex circuit;

FIG. 23 is an exploded perspective view of an emitter portion of a flex circuit assembly;

FIG. 24 is an exploded perspective view of a detector assembly embodiment;

FIGS. 25-26 are block diagrams of adjacent detector and stacked detector embodiments;

FIG. 27 is a block diagram of a finger clip embodiment of an attachment assembly;

FIG. 28 is a general block diagram of a detector pad;

FIGS. 29A-B are perspective views of detector pad embodiments;

FIGS. 30A-H are perspective bottom, perspective top, bottom, back, top, side cross sectional, side, and front cross sectional views of an emitter pad embodiment;

FIGS. 31A-H are perspective bottom, perspective top, top, back, bottom, side cross sectional, side, and front cross sectional views of a detector pad embodiment;

FIGS. 32A-H are perspective bottom, perspective top, top, back, bottom, side cross sectional, side, and front cross sectional views of a shoe box;

FIGS. 33A-H are perspective bottom, perspective top, top, back, bottom, side cross sectional, side, and front cross sectional views of a slim-finger emitter pad embodiment;

FIGS. 34A-H are perspective bottom, perspective top, top, back, bottom, side cross sectional, side, and front cross sectional views of a slim-finger detector pad embodiment;

FIGS. 35A-B are plan and cross sectional views, respectively, of a spring assembly embodiment;

FIGS. 36A-C are top, perspective and side views of a finger clip spring;

FIGS. 37A-D are top, back, bottom, and side views of a spring plate;

FIGS. 38A-D are front cross sectional, bottom, front and side cross sectional views of an emitter-pad shell;

FIGS. 39A-D are back, top, front and side cross sectional views of a detector-pad shell;

FIG. 40 is a general block diagram of a monitor and a sensor;

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FIGS. 41A-C are schematic diagrams of grid drive embodiments for a sensor having back-to-back diodes and an information element;

FIG. 42 is a schematic diagrams of a grid drive embodiment for an information element;

FIGS. 43A-C are schematic diagrams for grid drive readable information elements;

FIGS. 44A-B are cross sectional and side cut away views of a sensor cable;

FIG. 45 is a block diagram of a sensor controller embodiment; and

FIG. 46 is a detailed exploded perspective view of a multiple wavelength sensor embodiment.

DETAILED DESCRIPTION

Overview

In this application, reference is made to many blood parameters. Some references that have common shorthand designations are referenced through such shorthand designations. For example, as used herein, HbCO designates carboxyhemoglobin, HbMet designates methemoglobin, and Hbt designates total hemoglobin. Other shorthand designations such as COHb, MetHb, and tHb are also common in the art for these same constituents. These constituents are generally reported in terms of a percentage, often referred to as saturation, relative concentration or fractional saturation. Total hemoglobin is generally reported as a concentration in g/dL. The use of the particular shorthand designators presented in this application does not restrict the term to any particular manner in which the designated constituent is reported.

FIG. 1 illustrates a physiological measurement system 10 having a monitor 100 and a multiple wavelength sensor assembly 200 with enhanced measurement capabilities as compared with conventional pulse oximetry. The physiological measurement system 10 allows the monitoring of a person, including a patient. In particular, the multiple wavelength sensor assembly 200 allows the measurement of blood constituent and related parameters in addition to oxygen saturation and pulse rate. Alternatively, the multiple wavelength sensor assembly 200 allows the measurement of oxygen saturation and pulse rate with increased accuracy or robustness as compared with conventional pulse oximetry.

In one embodiment, the sensor assembly 200 is configured to plug into a monitor sensor port 110. Monitor keys 160 provide control over operating modes and alarms, to name a few. A display 170 provides readouts of measured parameters, such as oxygen saturation, pulse rate, HbCO and HbMet to name a few.

FIG. 2A illustrates a multiple wavelength sensor assembly 200 having a sensor 400 adapted to attach to a tissue site, a sensor cable 4400 and a monitor connector 210. In one embodiment, the sensor 400 is incorporated into a reusable finger clip adapted to removably attach to, and transmit light through, a fingertip. The sensor cable 4400 and monitor connector 210 are integral to the sensor 400, as shown. In alternative embodiments, the sensor 400 may be configured separately from the cable 4400 and connector 210.

FIGS. 2B-C illustrate alternative sensor embodiments, including a sensor 401 (FIG. 2B) partially disposable and partially reusable (resposable) and utilizing an adhesive attachment mechanism. Also shown is a sensor 402 (FIG. 2C) being disposable and utilizing an adhesive attachment mechanism. In other embodiments, a sensor may be configured to attach to various tissue sites other than a finger, such

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as a foot or an ear. Also a sensor may be configured as a reflectance or transreflectance device that attaches to a forehead or other tissue surface.

FIG. 3 illustrates a sensor assembly 400 having an emitter assembly 500, a detector assembly 2400, an interconnect assembly 1900 and an attachment assembly 2700. The emitter assembly 500 responds to drive signals received from a sensor controller 4500 in the monitor 100 via the cable 4400 so as to transmit optical radiation having a plurality of wavelengths into a tissue site. The detector assembly 2400 provides a sensor signal to the monitor 100 via the cable 4400 in response to optical radiation received after attenuation by the tissue site. The interconnect assembly 1900 provides electrical communication between the cable 4400 and both the emitter assembly 500 and the detector assembly 2400. The attachment assembly 2700 attaches the emitter assembly 500 and detector assembly 2400 to a tissue site, as described above. The emitter assembly 500 is described in further detail with respect to FIG. 5, below. The interconnect assembly 1900 is described in further detail with respect to FIG. 19, below. The detector assembly 2400 is described in further detail with respect to FIG. 24, below. The attachment assembly 2700 is described in further detail with respect to FIG. 27, below.

FIG. 4 illustrates a sensor 400 embodiment that removably attaches to a fingertip. The sensor 400 houses a multiple wavelength emitter assembly 500 and corresponding detector assembly 2400. A flex circuit assembly 1900 mounts the emitter and detector assemblies 500, 2400 and interconnects them to a multi-wire sensor cable 4400. Advantageously, the sensor 400 is configured in several respects for both wearer comfort and parameter measurement performance. The flex circuit assembly 1900 is configured to mechanically decouple the cable 4400 wires from the emitter and detector assemblies 500, 2400 to reduce pad stiffness and wearer discomfort. The pads 3000, 3100 are mechanically decoupled from shells 3800, 3900 to increase flexibility and wearer comfort. A spring 3600 is configured in hinged shells 3800, 3900 so that the pivot point of the finger clip is well behind the fingertip, improving finger attachment and more evenly distributing the clip pressure along the finger.

As shown in FIG. 4, the detector pad 3100 is structured to properly position a fingertip in relationship to the detector assembly 2400. The pads have flaps that block ambient light. The detector assembly 2400 is housed in an enclosure so as to reduce light piping from the emitter assembly to the detector assembly without passing through fingertip tissue. These and other features are described in detail below. Specifically, emitter assembly embodiments are described with respect to FIGS. 5-18. Interconnect assembly embodiments, including the flexible circuit assembly 1900, are described with respect to FIGS. 19-23. Detector assembly embodiments are described with respect to FIGS. 24-26. Attachment assembly embodiments are described with respect to FIGS. 27-39.

Emitter Assembly

FIG. 5 illustrates an emitter assembly 500 having an emitter array 700, a substrate 1200 and equalization 900. The emitter array 700 has multiple light emitting sources, each activated by addressing at least one row and at least one column of an electrical grid. The light emitting sources are capable of transmitting optical radiation having multiple wavelengths. The equalization 900 accounts for differences in tissue attenuation of the optical radiation across the multiple wavelengths so as to at least reduce wavelength-dependent variations in detected intensity. The substrate 1200 provides a physical mount for the emitter array and

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emitter-related equalization and a connection between the emitter array and the interconnection assembly. Advantageously, the substrate **1200** also provides a bulk temperature measurement so as to calculate the operating wavelengths for the light emitting sources. The emitter array **700** is described in further detail with respect to FIG. 7, below. Equalization is described in further detail with respect to FIG. 9, below. The substrate **1200** is described in further detail with respect to FIG. 12, below.

FIG. 6 illustrates an emitter assembly **500** embodiment having an emitter array **700**, an encapsulant **600**, an optical filter **1100** and a substrate **1200**. Various aspects of the emitter assembly **500** are described with respect to FIGS. 7-18, below. The emitter array **700** emits optical radiation having multiple wavelengths of predetermined nominal values, advantageously allowing multiple parameter measurements. In particular, the emitter array **700** has multiple light emitting diodes (LEDs) **710** that are physically arranged and electrically connected in an electrical grid to facilitate drive control, equalization, and minimization of optical pathlength differences at particular wavelengths. The optical filter **1100** is advantageously configured to provide intensity equalization across a specific LED subset. The substrate **1200** is configured to provide a bulk temperature of the emitter array **700** so as to better determine LED operating wavelengths. Emitter Array

FIG. 7 illustrates an emitter array **700** having multiple light emitters (LE) **710** capable of emitting light **702** having multiple wavelengths into a tissue site **1**. Row drivers **4530** and column drivers **4560** are electrically connected to the light emitters **710** and activate one or more light emitters **710** by addressing at least one row **720** and at least one column **740** of an electrical grid. In one embodiment, the light emitters **710** each include a first contact **712** and a second contact **714**. The first contact **712** of a first subset **730** of light emitters is in communication with a first conductor **720** of the electrical grid. The second contact **714** of a second subset **750** of light emitters is in communication with a second conductor **740**. Each subset comprises at least two light emitters, and at least one of the light emitters of the first and second subsets **730**, **750** are not in common. A detector **2400** is capable of detecting the emitted light **702** and outputting a sensor signal **2500** responsive to the emitted light **702** after attenuation by the tissue site **1**. As such, the sensor signal **2500** is indicative of at least one physiological parameter corresponding to the tissue site **1**, as described above.

FIG. 8 illustrates an emitter array **700** having LEDs **801** connected within an electrical grid of n rows and m columns totaling $n+m$ drive lines **4501**, **4502**, where n and m integers greater than one. The electrical grid advantageously minimizes the number of drive lines required to activate the LEDs **801** while preserving flexibility to selectively activate individual LEDs **801** in any sequence and multiple LEDs **801** simultaneously. The electrical grid also facilitates setting LED currents so as to control intensity at each wavelength, determining operating wavelengths and monitoring total grid current so as to limit power dissipation. The emitter array **700** is also physically configured in rows **810**. This physical organization facilitates clustering LEDs **801** according to wavelength so as to minimize pathlength variations and facilitates equalization of LED intensities.

As shown in FIG. 8, one embodiment of an emitter array **700** comprises up to sixteen LEDs **801** configured in an electrical grid of four rows **810** and four columns **820**. Each of the four row drive lines **4501** provide a common anode connection to four LEDs **801**, and each of the four column

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drive lines **4502** provide a common cathode connection to four LEDs **801**. Thus, the sixteen LEDs **801** are advantageously driven with only eight wires, including four anode drive lines **812** and four cathode drive lines **822**. This compares favorably to conventional common anode or cathode LED configurations, which require more drive lines. In a particular embodiment, the emitter array **700** is partially populated with eight LEDs having nominal wavelengths as shown in TABLE 1. Further, LEDs having wavelengths in the range of 610-630 nm are grouped together in the same row. The emitter array **700** is adapted to a physiological measurement system **10** (FIG. 1) for measuring HbCO and/or METHb in addition to S_pO_2 and pulse rate.

TABLE 1

Nominal LED Wavelengths			
LED	λ	Row	Col
D1	630	1	1
D2	620	1	2
D3	610	1	3
D4		1	4
D5	700	2	1
D6	730	2	2
D7	660	2	3
D8	805	2	4
D9		3	1
D10		3	2
D11		3	3
D12	905	3	4
D13		4	1
D14		4	2
D15		4	3
D16		4	4

Also shown in FIG. 8, row drivers **4530** and column drivers **4560** located in the monitor **100** selectively activate the LEDs **801**. In particular, row and column drivers **4530**, **4560** function together as switches to Vcc and current sinks, respectively, to activate LEDs and as switches to ground and Vcc, respectively, to deactivate LEDs. This push-pull drive configuration advantageously prevents parasitic current flow in deactivated LEDs. In a particular embodiment, only one row drive line **4501** is switched to Vcc at a time. One to four column drive lines **4502**, however, can be simultaneously switched to a current sink so as to simultaneously activate multiple LEDs within a particular row. Activation of two or more LEDs of the same wavelength facilitates intensity equalization, as described with respect to FIGS. 9-11, below. LED drivers are described in further detail with respect to FIG. 45, below.

Although an emitter assembly is described above with respect to an array of light emitters each configured to transmit optical radiation centered around a nominal wavelength, in another embodiment, an emitter assembly advantageously utilizes one or more tunable broadband light sources, including the use of filters to select the wavelength, so as to minimize wavelength-dependent pathlength differences from emitter to detector. In yet another emitter assembly embodiment, optical radiation from multiple emitters each configured to transmit optical radiation centered around a nominal wavelength is funneled to a tissue site point so as to minimize wavelength-dependent pathlength differences. This funneling may be accomplished with fiberoptics or mirrors, for example. In further embodiments, the LEDs **801** can be configured with alternative orientations with correspondingly different drivers among various other configurations of LEDs, drivers and interconnecting conductors.

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Equalization

FIG. 9 illustrate a physiological parameter measurement system 10 having a controller 4500, an emitter assembly 500, a detector assembly 2400 and a front-end 4030. The emitter assembly 500 is configured to transmit optical radiation having multiple wavelengths into the tissue site 1. The detector assembly 2400 is configured to generate a sensor signal 2500 responsive to the optical radiation after tissue attenuation. The front-end 4030 conditions the sensor signal 2500 prior to analog-to-digital conversion (ADC).

FIG. 9 also generally illustrates equalization 900 in a physiological measurement system 10 operating on a tissue site 1. Equalization encompasses features incorporated into the system 10 in order to provide a sensor signal 2500 that falls well within the dynamic range of the ADC across the entire spectrum of emitter wavelengths. In particular, equalization compensates for the imbalance in tissue light absorption due to Hb and HbO₂ 910. Specifically, these blood constituents attenuate red wavelengths greater than IR wavelengths. Ideally, equalization 900 balances this unequal attenuation. Equalization 900 can be introduced anywhere in the system 10 from the controller 4500 to front-end 4000 and can include compensatory attenuation versus wavelength, as shown, or compensatory amplification versus or both.

Equalization can be achieved to a limited extent by adjusting drive currents from the controller 4500 and front-end 4030 amplification accordingly to wavelength so as to compensate for tissue absorption characteristics. Signal demodulation constraints, however, limit the magnitude of these adjustments. Advantageously, equalization 900 is also provided along the optical path from emitters 500 to detector 2400. Equalization embodiments are described in further detail with respect to FIGS. 10-11, below.

FIGS. 10A-D illustrate various equalization embodiments having an emitter array 700 adapted to transmit optical radiation into a tissue site 1 and a detector assembly 2400 adapted to generate a sensor signal 2500 responsive to the optical radiation after tissue attenuation. FIG. 10A illustrates an optical filter 1100 that attenuates at least a portion of the optical radiation before it is transmitted into a tissue site 1. In particular, the optical filter 1100 attenuates at least a portion of the IR wavelength spectrum of the optical radiation so as to approximate an equalization curve 900 (FIG. 9). FIG. 10B illustrates an optical filter 1100 that attenuates at least a portion of the optical radiation after it is attenuated by a tissue site 1, where the optical filter 1100 approximates an equalization curve 900 (FIG. 9).

FIG. 10C illustrates an emitter array 700 where at least a portion of the emitter array generates one or more wavelengths from multiple light emitters 710 of the same wavelength. In particular, the same-wavelength light emitters 710 boost at least a portion of the red wavelength spectrum so as to approximately equalize the attenuation curves 910 (FIG. 9). FIG. 10D illustrates a detector assembly 2400 having multiple detectors 2610, 2620 selected so as to equalize the attenuation curves 910 (FIG. 9). To a limited extent, optical equalization can also be achieved by selection of particular emitter array 700 and detector 2400 components, e.g. LEDs having higher output intensities or detectors having higher sensitivities at red wavelengths. Although equalization embodiments are described above with respect to red and IR wavelengths, these equalization embodiments can be applied to equalize tissue characteristics across any portion of the optical spectrum.

FIGS. 11A-C illustrates an optical filter 1100 for an emitter assembly 500 that advantageously provides optical equalization, as described above. LEDs within the emitter

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array 700 may be grouped according to output intensity or wavelength or both. Such a grouping facilitates equalization of LED intensity across the array. In particular, relatively low tissue absorption and/or relatively high output intensity LEDs can be grouped together under a relatively high attenuation optical filter. Likewise, relatively low tissue absorption and/or relatively low output intensity LEDs can be grouped together without an optical filter or under a relatively low or negligible attenuation optical filter. Further, high tissue absorption and/or low intensity LEDs can be grouped within the same row with one or more LEDs of the same wavelength being simultaneously activated, as described with respect to FIG. 10C, above. In general, there can be any number of LED groups and any number of LEDs within a group. There can also be any number of optical filters corresponding to the groups having a range of attenuation, including no optical filter and/or a "clear" filter having negligible attenuation.

As shown in FIGS. 11A-C, a filtering media may be advantageously added to an encapsulant that functions both as a cover to protect LEDs and bonding wires and as an optical filter 1100. In one embodiment, a filtering media 1100 encapsulates a select group of LEDs and a clear media 600 (FIG. 6) encapsulates the entire array 700 and the filtering media 1000 (FIG. 6). In a particular embodiment, corresponding to TABLE 1, above, five LEDs nominally emitting at 660-905 nm are encapsulated with both a filtering media 1100 and an overlying clear media 600 (FIG. 6), i.e. attenuated. In a particular embodiment, the filtering media 1100 is a 40:1 mixture of a clear encapsulant (EPO-TEK OG147-7) and an opaque encapsulate (EPO-TEK OG147) both available from Epoxy Technology, Inc., Billerica, Mass. Three LEDs nominally emitting at 610-630 nm are only encapsulated with the clear media 600 (FIG. 6), i.e. unattenuated. In alternative embodiments, individual LEDs may be singly or multiply encapsulated according to tissue absorption and/or output intensity. In other alternative embodiments, filtering media may be separately attachable optical filters or a combination of encapsulants and separately attachable optical filters. In a particular embodiment, the emitter assembly 500 has one or more notches along each side proximate the component end 1305 (FIG. 13) for retaining one or more clip-on optical filters.

Substrate

FIG. 12 illustrates light emitters 710 configured to transmit optical radiation 1201 having multiple wavelengths in response to corresponding drive currents 1210. A thermal mass 1220 is disposed proximate the emitters 710 so as to stabilize a bulk temperature 1202 for the emitters. A temperature sensor 1230 is thermally coupled to the thermal mass 1220, wherein the temperature sensor 1230 provides a temperature sensor output 1232 responsive to the bulk temperature 1202 so that the wavelengths are determinable as a function of the drive currents 1210 and the bulk temperature 1202.

In one embodiment, an operating wavelength λ_a of each light emitter 710 is determined according to EQ. 3

$$\lambda_a = f(T_b, I_{drive}, \Sigma I_{drive}) \quad (3)$$

where T_b is the bulk temperature, I_{drive} is the drive current for a particular light emitter, as determined by the sensor controller 4500 (FIG. 45), described below, and ΣI_{drive} is the total drive current for all light emitters. In another embodiment, temperature sensors are configured to measure the temperature of each light emitter 710 and an operating wavelength λ_a of each light emitter 710 is determined according to EQ. 4

$$\lambda_a = f(T_a, I_{drive}, \Sigma I_{drive}) \quad (4)$$

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where T_a is the temperature of a particular light emitter, I_{drive} is the drive current for that light emitter and ΣI_{drive} is the total drive current for all light emitters.

In yet another embodiment, an operating wavelength for each light emitter is determined by measuring the junction voltage for each light emitter 710. In a further embodiment, the temperature of each light emitter 710 is controlled, such as by one or more Peltier cells coupled to each light emitter 710, and an operating wavelength for each light emitter 710 is determined as a function of the resulting controlled temperature or temperatures. In other embodiments, the operating wavelength for each light emitter 710 is determined directly, for example by attaching a charge coupled device (CCD) to each light emitter or by attaching a fiberoptic to each light emitter and coupling the fiberoptics to a wavelength measuring device, to name a few.

FIGS. 13-18 illustrate one embodiment of a substrate 1200 configured to provide thermal conductivity between an emitter array 700 (FIG. 8) and a thermistor 1540 (FIG. 16). In this manner, the resistance of the thermistor 1540 (FIG. 16) can be measured in order to determine the bulk temperature of LEDs 801 (FIG. 8) mounted on the substrate 1200. The substrate 1200 is also configured with a relatively significant thermal mass, which stabilizes and normalizes the bulk temperature so that the thermistor measurement of bulk temperature is meaningful.

FIGS. 13-14 illustrate a substrate 1200 having a component side 1301, a solder side 1302, a component end 1305 and a connector end 1306. Alignment notches 1310 are disposed between the ends 1305, 1306. The substrate 1200 further has a component layer 1401, inner layers 1402-1405 and a solder layer 1406. The inner layers 1402-1405, e.g. inner layer 1402 (FIG. 18), have substantial metallized areas 1411 that provide a thermal mass 1220 (FIG. 12) to stabilize a bulk temperature for the emitter array 700 (FIG. 12). The metallized areas 1411 also function to interconnect component pads 1510 and wire bond pads 1520 (FIG. 15) to the connector 1530.

FIGS. 15-16 illustrate a substrate 1200 having component pads 1510 and wire bond pads 1520 at a component end 1305. The component pads 1510 mount and electrically connect a first side (anode or cathode) of the LEDs 801 (FIG. 8) to the substrate 1200. Wire bond pads 1520 electrically connect a second side (cathode or anode) of the LEDs 801 (FIG. 8) to the substrate 1200. The connector end 1306 has a connector 1530 with connector pads 1532, 1534 that mount and electrically connect the emitter assembly 500 (FIG. 23), including the substrate 1200, to the flex circuit 2200 (FIG. 22). Substrate layers 1401-1406 (FIG. 14) have traces that electrically connect the component pads 1510 and wire bond pads 1520 to the connector 1532-1534. A thermistor 1540 is mounted to thermistor pads 1550 at the component end 1305, which are also electrically connected with traces to the connector 1530. Plated thru holes electrically connect the connector pads 1532, 1534 on the component and solder sides 1301, 1302, respectively.

FIG. 17 illustrates the electrical layout of a substrate 1200. A portion of the LEDs 801, including D1-D4 and D13-D16 have cathodes physically and electrically connected to component pads 1510 (FIG. 15) and corresponding anodes wire bonded to wire bond pads 1520. Another portion of the LEDs 801, including D5-D8 and D9-D12, have anodes physically and electrically connected to component pads 1510 (FIG. 15) and corresponding cathodes wire bonded to wire bond pads 1520. The connector 1530

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has row pinouts J21-J24, column pinouts J31-J34 and thermistor pinouts J40-J41 for the LEDs 801 and thermistor 1540. Interconnect Assembly

FIG. 19 illustrates an interconnect assembly 1900 that mounts the emitter assembly 500 and detector assembly 2400, connects to the sensor cable 4400 and provides electrical communications between the cable and each of the emitter assembly 500 and detector assembly 2400. In one embodiment, the interconnect assembly 1900 is incorporated with the attachment assembly 2700, which holds the emitter and detector assemblies to a tissue site. An interconnect assembly embodiment utilizing a flexible (flex) circuit is described with respect to FIGS. 20-24, below.

FIG. 20 illustrates an interconnect assembly 1900 embodiment having a circuit substrate 2200, an emitter mount 2210, a detector mount 2220 and a cable connector 2230. The emitter mount 2210, detector mount 2220 and cable connector 2230 are disposed on the circuit substrate 2200. The emitter mount 2210 is adapted to mount an emitter assembly 500 having multiple emitters. The detector mount 2220 is adapted to mount a detector assembly 2400 having a detector. The cable connector 2230 is adapted to attach a sensor cable 4400. A first plurality of conductors 2040 disposed on the circuit substrate 2200 electrically interconnects the emitter mount 2210 and the cable connector 2230. A second plurality of conductors 2050 disposed on the circuit substrate 2200 electrically interconnects the detector mount 2220 and the cable connector 2230. A decoupling 2060 disposed proximate the cable connector 2230 substantially mechanically isolates the cable connector 2230 from both the emitter mount 2210 and the detector mount 2220 so that sensor cable stiffness is not translated to the emitter assembly 500 or the detector assembly 2400. A shield 2070 is adapted to fold over and shield one or more wires or pairs of wires of the sensor cable 4400.

FIG. 21 illustrates a flex circuit assembly 1900 having a flex circuit 2200, an emitter assembly 500 and a detector assembly 2400, which is configured to terminate the sensor end of a sensor cable 4400. The flex circuit assembly 1900 advantageously provides a structure that electrically connects yet mechanically isolates the sensor cable 4400, the emitter assembly 500 and the detector assembly 2400. As a result, the mechanical stiffness of the sensor cable 4400 is not translated to the sensor pads 3000, 3100 (FIGS. 30-31), allowing a comfortable finger attachment for the sensor 200 (FIG. 1). In particular, the emitter assembly 500 and detector assembly 2400 are mounted to opposite ends 2201, 2202 (FIG. 22) of an elongated flex circuit 2200. The sensor cable 4400 is mounted to a cable connector 2230 extending from a middle portion of the flex circuit 2200. Detector wires 4470 are shielded at the flex circuit junction by a fold-over conductive ink flap 2240, which is connected to a cable inner shield 4450. The flex circuit 2200 is described in further detail with respect to FIG. 22. The emitter portion of the flex circuit assembly 1900 is described in further detail with respect to FIG. 23. The detector assembly 2400 is described with respect to FIG. 24. The sensor cable 4400 is described with respect to FIGS. 44A-B, below.

FIG. 22 illustrates a sensor flex circuit 2200 having an emitter end 2201, a detector end 2202, an elongated interconnect 2204, 2206 between the ends 2201, 2202 and a cable connector 2230 extending from the interconnect 2204, 2206. The emitter end 2201 forms a "head" having emitter solder pads 2210 for attaching the emitter assembly 500 (FIG. 6) and mounting ears 2214 for attaching to the emitter pad 3000 (FIG. 30B), as described below. The detector end 2202 has detector solder pads for attaching the detector 2410 (FIG.

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24). The interconnect **2204** between the emitter end **2201** and the cable connector **2230** forms a “neck,” and the interconnect **2206** between the detector end **2202** and the cable connector **2230** forms a “tail.” The cable connector **2230** forms “wings” that extend from the interconnect **2204**, **2206** between the neck **2204** and tail **2206**. A conductive ink flap **2240** connects to the cable inner shield **4450** (FIGS. **44A-B**) and folds over to shield the detector wires **4470** (FIGS. **44A-B**) soldered to the detector wire pads **2236**. The outer wire pads **2238** connect to the remaining cable wires **4430** (FIGS. **44A-B**). The flex circuit **2200** has top coverlay, top ink, inner coverlay, trace, trace base, bottom ink and bottom coverlay layers.

The flex circuit **2200** advantageously provides a connection between a multiple wire sensor cable **4400** (FIGS. **44A-B**), a multiple wavelength emitter assembly **500** (FIG. **6**) and a detector assembly **2400** (FIG. **24**) without rendering the emitter and detector assemblies unwieldy and stiff. In particular, the wings **2230** provide a relatively large solder pad area **2232** that is narrowed at the neck **2204** and tail **2206** to mechanically isolate the cable **4400** (FIGS. **44A-B**) from the remainder of the flex circuit **2200**. Further, the neck **2206** is folded (see FIG. **4**) for installation in the emitter pad **3000** (FIGS. **30A-H**) and acts as a flexible spring to further mechanically isolate the cable **4400** (FIGS. **44A-B**) from the emitter assembly **500** (FIG. **4**). The tail **2206** provides an integrated connectivity path between the detector assembly **2400** (FIG. **24**) mounted in the detector pad **3100** (FIGS. **31A-H**) and the cable connector **2230** mounted in the opposite emitter pad **3000** (FIGS. **30A-H**).

FIG. **23** illustrates the emitter portion of the flex circuit assembly **1900** (FIG. **21**) having the emitter assembly **500**. The emitter assembly connector **1530** is attached to the emitter end **2210** of the flex circuit **2200** (FIG. **22**). In particular, reflow solder **2330** connects thru hole pads **1532**, **1534** of the emitter assembly **500** to corresponding emitter pads **2310** of the flex circuit **2200** (FIG. **22**).

FIG. **24** illustrates a detector assembly **2400** including a detector **2410**, solder pads **2420**, copper mesh tape **2430**, an EMI shield **2440** and foil **2450**. The detector **2410** is soldered **2460** chip side down to detector solder pads **2420** of the flex circuit **2200**. The detector solder joint and detector ground pads **2420** are wrapped with the Kapton tape **2470**. EMI shield tabs **2442** are folded onto the detector pads **2420** and soldered. The EMI shield walls are folded around the detector **2410** and the remaining tabs **2442** are soldered to the back of the EMI shield **2440**. The copper mesh tape **2430** is cut to size and the shielded detector and flex circuit solder joint are wrapped with the copper mesh tape **2430**. The foil **2450** is cut to size with a predetermined aperture **2452**. The foil **2450** is wrapped around shielded detector with the foil side in and the aperture **2452** is aligned with the EMI shield grid **2444**.

Detector Assembly

FIG. **25** illustrates an alternative detector assembly **2400** embodiment having adjacent detectors. Optical radiation having multiple wavelengths generated by emitters **700** is transmitted into a tissue site **1**. Optical radiation at a first set of wavelengths is detected by a first detector **2510**, such as, for example, a Si detector. Optical radiation at a second set of wavelengths is detected by a second detector **2520**, such as, for example, a GaAs detector.

FIG. **26** illustrates another alternative detector assembly **2400** embodiment having stacked detectors coaxial along a light path. Optical radiation having multiple wavelengths generated by emitters **700** is transmitted into a tissue site **1**. Optical radiation at a first set of wavelengths is detected by

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a first detector **2610**. Optical radiation at a second set of wavelengths passes through the first detector **2610** and is detected by a second detector **2620**. In a particular embodiment, a silicon (Si) detector and a gallium arsenide (GaAs) detector are used. The Si detector is placed on top of the GaAs detector so that light must pass through the Si detector before reaching the GaAs detector. The Si detector can be placed directly on top of the GaAs detector or the Si and GaAs detector can be separated by some other medium, such as a transparent medium or air. In another particular embodiment, a germanium detector is used instead of the GaAs detector. Advantageously, the stacked detector arrangement minimizes error caused by pathlength differences as compared with the adjacent detector embodiment.

Finger Clip

FIG. **27** illustrates a finger clip embodiment **2700** of a physiological sensor attachment assembly. The finger clip **2700** is configured to removably attach an emitter assembly **500** (FIG. **6**) and detector assembly **2400** (FIG. **24**), interconnected by a flex circuit assembly **1900**, to a fingertip. The finger clip **2700** has an emitter shell **3800**, an emitter pad **3000**, a detector pad **2800** and a detector shell **3900**. The emitter shell **3800** and the detector shell **3900** are rotatably connected and urged together by the spring assembly **3500**. The emitter pad **3000** is fixedly retained by the emitter shell. The emitter assembly **500** (FIG. **6**) is mounted proximate the emitter pad **3000** and adapted to transmit optical radiation having a plurality of wavelengths into fingertip tissue. The detector pad **2800** is fixedly retained by the detector shell **3900**. The detector assembly **3500** is mounted proximate the detector pad **2800** and adapted to receive the optical radiation after attenuation by fingertip tissue.

FIG. **28** illustrates a detector pad **2800** advantageously configured to position and comfortably maintain a fingertip relative to a detector assembly for accurate sensor measurements. In particular, the detector pad has fingertip positioning features including a guide **2810**, a contour **2820** and a stop **2830**. The guide **2810** is raised from the pad surface **2803** and narrows as the guide **2810** extends from a first end **2801** to a second end **2802** so as to increasingly conform to a fingertip as a fingertip is inserted along the pad surface **2803** from the first end **2801**. The contour **2820** has an indentation defined along the pad surface **2803** generally shaped to conform to a fingertip positioned over a detector aperture **2840** located within the contour **2820**. The stop **2830** is raised from the pad surface **2803** so as to block the end of a finger from inserting beyond the second end **2802**. FIGS. **29A-B** illustrate detector pad embodiments **3100**, **3400** each having a guide **2810**, a contour **2820** and a stop **2830**, described in further detail with respect to FIGS. **31** and **34**, respectively.

FIGS. **30A-H** illustrate an emitter pad **3000** having emitter pad flaps **3010**, an emitter window **3020**, mounting pins **3030**, an emitter assembly cavity **3040**, isolation notches **3050**, a flex circuit notch **3070** and a cable notch **3080**. The emitter pad flaps **3010** overlap with detector pad flaps **3110** (FIGS. **31A-H**) to block ambient light. The emitter window **3020** provides an optical path from the emitter array **700** (FIG. **8**) to a tissue site. The mounting pins **3030** accommodate apertures in the flex circuit mounting ears **2214** (FIG. **22**), and the cavity **3040** accommodates the emitter assembly **500** (FIG. **21**). Isolation notches **3050** mechanically decouple the shell attachment **3060** from the remainder of the emitter pad **3000**. The flex circuit notch **3070** accommodates the flex circuit tail **2206** (FIG. **22**) routed to the detector pad **3100** (FIGS. **31A-H**). The cable notch **3080**

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accommodates the sensor cable **4400** (FIGS. **44A-B**). FIGS. **33A-H** illustrate an alternative slim finger emitter pad **3300** embodiment.

FIGS. **31A-H** illustrate a detector pad **3100** having detector pad flaps **3110**, a shoe box cavity **3120** and isolation notches **3150**. The detector pad flaps **3110** overlap with emitter pad flaps **3010** (FIGS. **30A-H**), interleaving to block ambient light. The shoe box cavity **3120** accommodates a shoe box **3200** (FIG. **32A-H**) described below. Isolation notches **3150** mechanically decouple the attachment points **3160** from the remainder of the detector pad **3100**. FIGS. **34A-H** illustrate an alternative slim finger detector pad **3400** embodiment.

FIGS. **32A-H** illustrate a shoe box **3200** that accommodates the detector assembly **2400** (FIG. **24**). A detector window **3210** provides an optical path from a tissue site to the detector **2410** (FIG. **24**). A flex circuit notch **3220** accommodates the flex circuit tail **2206** (FIG. **22**) routed from the emitter pad **3000** (FIGS. **30A-H**). In one embodiment, the shoe box **3200** is colored black or other substantially light absorbing color and the emitter pad **3000** and detector pad **3100** are each colored white or other substantially light reflecting color.

FIGS. **35-37** illustrate a spring assembly **3500** having a spring **3600** configured to urge together an emitter shell **3800** (FIG. **46**) and a detector shell **3900**. The detector shell is rotatably connected to the emitter shell. The spring is disposed between the shells **3800**, **3900** and adapted to create a pivot point along a finger gripped between the shells that is substantially behind the fingertip. This advantageously allows the shell hinge **3810**, **3910** (FIGS. **38-39**) to expand so as to distribute finger clip force along the inserted finger, comfortably keeping the fingertip in position over the detector without excessive force.

As shown in FIGS. **36A-C**, the spring **3600** has coils **3610**, an emitter shell leg **3620** and a detector shell leg **3630**. The emitter shell leg **3620** presses against the emitter shell **3800** (FIGS. **38A-D**) proximate a grip **3820** (FIGS. **38A-D**). The detector shell legs **3630** extend along the detector shell **3900** (FIGS. **39A-D**) to a spring plate **3700** (FIGS. **37A-D**) attachment point. The coil **3610** is secured by hinge pins **410** (FIG. **46**) and is configured to wind as the finger clip is opened, reducing its diameter and stress accordingly.

As shown in FIGS. **37A-D** the spring plate **3700** has attachment apertures **3710**, spring leg slots **3720**, and a shelf **3730**. The attachment apertures **3710** accept corresponding shell posts **3930** (FIGS. **39A-D**) so as to secure the spring plate **3700** to the detector shell **3900** (FIG. **39A-D**). Spring legs **3630** (FIG. **36A-C**) are slidably anchored to the detector shell **3900** (FIG. **39A-D**) by the shelf **3730**, advantageously allowing the combination of spring **3600**, shells **3800**, **3900** and hinges **3810**, **3910** to adjust to various finger sizes and shapes.

FIGS. **38-39** illustrate the emitter and detector shells **3800**, **3900**, respectively, having hinges **3810**, **3910** and grips **3820**, **3920**. Hinge apertures **3812**, **3912** accept hinge pins **410** (FIG. **46**) so as to create a finger clip. The detector shell hinge aperture **3912** is elongated, allowing the hinge to expand to accommodate a finger.

Monitor And Sensor

FIG. **40** illustrates a monitor **100** and a corresponding sensor assembly **200**, as described generally with respect to FIGS. **1-3**, above. The sensor assembly **200** has a sensor **400** and a sensor cable **4400**. The sensor **400** houses an emitter assembly **500** having emitters responsive to drivers within a sensor controller **4500** so as to transmit optical radiation into a tissue site. The sensor **400** also houses a detector assembly

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2400 that provides a sensor signal **2500** responsive to the optical radiation after tissue attenuation. The sensor signal **2500** is filtered, amplified, sampled and digitized by the front-end **4030** and input to a DSP (digital signal processor) **4040**, which also commands the sensor controller **4500**. The sensor cable **4400** electrically communicates drive signals from the sensor controller **4500** to the emitter assembly **500** and a sensor signal **2500** from the detector assembly **2400** to the front-end **4030**. The sensor cable **4400** has a monitor connector **210** that plugs into a monitor sensor port **110**.

In one embodiment, the monitor **100** also has a reader **4020** capable of obtaining information from an information element (IE) in the sensor assembly **200** and transferring that information to the DSP **4040**, to another processor or component within the monitor **100**, or to an external component or device that is at least temporarily in communication with the monitor **100**. In an alternative embodiment, the reader function is incorporated within the DSP **4040**, utilizing one or more of DSP I/O, ADC, DAC features and corresponding processing routines, as examples.

In one embodiment, the monitor connector **210** houses the information element **4000**, which may be a memory device or other active or passive electrical component. In a particular embodiment, the information element **4000** is an EPROM, or other programmable memory, or an EEPROM, or other reprogrammable memory, or both. In an alternative embodiment, the information element **4000** is housed within the sensor **400**, or an information element **4000** is housed within both the monitor connector **4000** and the sensor **400**. In yet another embodiment, the emitter assembly **500** has an information element **4000**, which is read in response to one or more drive signals from the sensor controller **4500**, as described with respect to FIGS. **41-43**, below. In a further embodiment, a memory information element is incorporated into the emitter array **700** (FIG. **8**) and has characterization information relating to the LEDs **801** (FIG. **8**). In one advantageous embodiment, trend data relating to slowly varying parameters, such as perfusion index, HbCO or METHb, to name a few, are stored in an IE memory device, such as EEPROM.

Back-to-Back LEDs

FIGS. **41-43** illustrate alternative sensor embodiments. A sensor controller **4500** configured to activate an emitter array **700** (FIG. **7**) arranged in an electrical grid, is described with respect to FIG. **7**, above. Advantageously, a sensor controller **4500** so configured is also capable of driving a conventional two-wavelength (red and IR) sensor **4100** having back-to-back LEDs **4110**, **4120** or an information element **4300** or both.

FIG. **41A** illustrates a sensor **4100** having an electrical grid **4130** configured to activate light emitting sources by addressing at least one row conductor and at least one column conductor. A first LED **4110** and a second LED **4120** are configured in a back-to-back arrangement so that a first contact **4152** is connected to a first LED **4110** cathode and a second LED **4120** anode and a second contact **4154** is connected to a first LED **4110** anode and a second LED **4120** cathode. The first contact **4152** is in communications with a first row conductor **4132** and a first column conductor **4134**. The second contact is in communications with a second row conductor **4136** and a second column conductor **4138**. The first LED **4110** is activated by addressing the first row conductor **4132** and the second column conductor **4138**. The second LED **4120** is activated by addressing the second row conductor **4136** and the first column conductor **4134**.

FIG. **41B** illustrates a sensor cable **4400** embodiment capable of communicating signals between a monitor **100**

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and a sensor **4100**. The cable **4400** has a first row input **4132**, a first column input **4134**, a second row input **4136** and a second column input **4138**. A first output **4152** combines the first row input **4132** and the first column input **4134**. A second output **4154** combines a second row input **4136** and second column input **4138**.

FIG. **41C** illustrates a monitor **100** capable of communicating drive signals to a sensor **4100**. The monitor **4400** has a first row signal **4132**, a first column signal **4134**, a second row signal **4136** and a second column signal **4138**. A first output signal **4152** combines the first row signal **4132** and the first column signal **4134**. A second output signal **4154** combines a second row signal **4136** and second column signal **4138**.

Information Elements

FIGS. **42-43** illustrate information element **4200-4300** embodiments in communications with emitter array drivers configured to activate light emitters connected in an electrical grid. The information elements are configured to provide information as DC values, AC values or a combination of DC and AC values in response corresponding DC, AC or combination DC and AC electrical grid drive signals. FIG. **42** illustrates information element embodiment **4200** advantageously driven directly by an electrical grid having rows **710** and columns **720**. In particular, the information element **4200** has a series connected resistor R_2 **4210** and diode **4220** connected between a row line **710** and a column line **720** of an electrical grid. In this manner, the resistor R_2 value can be read in a similar manner that LEDs **810** (FIG. **8**) are activated. The diode **4220** is oriented, e.g. anode to row and cathode to column as the LEDs so as to prevent parasitic currents from unwanted activation of LEDs **810** (FIG. **8**).

FIGS. **43A-C** illustrate other embodiments where the value of R_1 is read with a DC grid drive current and a corresponding grid output voltage level. In other particular embodiments, the combined values of R_1 , R_2 and C or, alternatively, R_1 , R_2 and L are read with a varying (AC) grid drive currents and a corresponding grid output voltage waveform. As one example, a step in grid drive current is used to determine component values from the time constant of a corresponding rise in grid voltage. As another example, a sinusoidal grid drive current is used to determine component values from the magnitude or phase or both of a corresponding sinusoidal grid voltage. The component values determined by DC or AC electrical grid drive currents can represent sensor types, authorized suppliers or manufacturers, emitter wavelengths among others. Further, a diode D (FIG. **43C**) can be used to provide one information element reading R_1 at one drive level or polarity and another information element reading, combining R_1 and R_2 , at a second drive level or polarity, i.e. when the diode is forward biased.

Passive information element **4300** embodiments may include any of various combinations of resistors, capacitors or inductors connected in series and parallel, for example. Other information element **4300** embodiments connected to an electrical grid and read utilizing emitter array drivers incorporate other passive components, active components or memory components, alone or in combination, including transistor networks, PROMs, ROMs, EPROMs, EEPROMs, gate arrays and PLAs to name a few.

Sensor Cable

FIGS. **44A-B** illustrate a sensor cable **4400** having an outer jacket **4410**, an outer shield **4420**, multiple outer wires **4430**, an inner jacket **4440**, an inner shield **4450**, a conductive polymer **4460** and an inner twisted wire pair **4470**. The

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outer wires **4430** are advantageously configured to compactly carry multiple drive signals to the emitter array **700** (FIG. **7**). In one embodiment, there are twelve outer wires **4430** corresponding to four anode drive signals **4501** (FIG. **45**), four cathode drive signals **4502** (FIG. **45**), two thermistor pinouts **1450** (FIG. **15**) and two spares. The inner twisted wire pair **4470** corresponds to the sensor signal **2500** (FIG. **25**) and is extruded within the conductive polymer **4460** so as to reduce triboelectric noise. The shields **4420**, **4450** and the twisted pair **4470** boost EMI and crosstalk immunity for the sensor signal **2500** (FIG. **25**).

Controller

FIG. **45** illustrates a sensor controller **4500** located in the monitor **100** (FIG. **1**) and configured to provide anode drive signals **4501** and cathode drive signals **4502** to the emitter array **700** (FIG. **7**). The DSP (digital signal processor) **4040**, which performs signal processing functions for the monitor, also provides commands **4042** to the sensor controller **4500**. These commands determine drive signal **4501**, **4502** levels and timing. The sensor controller **4500** has a command register **4510**, an anode selector **4520**, anode drivers **4530**, current DACs (digital-to-analog converters) **4540**, a current multiplexer **4550**, cathode drivers **4560**, a current meter **4570** and a current limiter **4580**. The command register **4510** provides control signals responsive to the DSP commands **4042**. In one embodiment, the command register **4510** is a shift register that loads serial command data **4042** from the DSP **4040** and synchronously sets output bits that select or enable various functions within the sensor controller **4500**, as described below.

As shown in FIG. **45**, the anode selector **4520** is responsive to anode select **4516** inputs from the command register **4510** that determine which emitter array row **810** (FIG. **8**) is active. Accordingly, the anode selector **4520** sets one of the anode on **4522** outputs to the anode drivers **4530**, which pulls up to V_{cc} one of the anode outputs **4501** to the emitter array **700** (FIG. **8**).

Also shown in FIG. **45**, the current DACs **4540** are responsive to command register data **4519** that determines the currents through each emitter array column **820** (FIG. **8**). In one embodiment, there are four, 12-bit DACs associated with each emitter array column **820** (FIG. **8**), sixteen DACs in total. That is, there are four DAC outputs **4542** associated with each emitter array column **820** (FIG. **8**) corresponding to the currents associated with each row **810** (FIG. **8**) along that column **820** (FIG. **8**). In a particular embodiment, all sixteen DACs **4540** are organized as a single shift register, and the command register **4510** serially clocks DAC data **4519** into the DACs **4540**. A current multiplexer **4550** is responsive to cathode on **4518** inputs from the command register **4510** and anode on **4522** inputs from the anode selector **4520** so as to convert the appropriate DAC outputs **4542** to current set **4552** inputs to the cathode drivers **4560**. The cathode drivers **4560** are responsive to the current set **4552** inputs to pull down to ground one to four of the cathode outputs **4502** to the emitter array **700** (FIG. **8**).

The current meter **4570** outputs a current measure **4572** that indicates the total LED current driving the emitter array **700** (FIG. **8**). The current limiter **4580** is responsive to the current measure **4572** and limits specified by the command register **4510** so as to prevent excessive power dissipation by the emitter array **700** (FIG. **8**). The current limiter **4580** provides an enable **4582** output to the anode selector **4520**. A Hi Limit **4512** input specifies the higher of two preset current limits. The current limiter **4580** latches the enable **4582** output in an off condition when the current limit is

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exceeded, disabling the anode selector **4520**. A trip reset **4514** input resets the enable **4582** output to re-enable the anode selector **4520**.

Sensor Assembly

As shown in FIG. **46**, the sensor **400** has an emitter shell **3800**, an emitter pad **3000**, a flex circuit assembly **2200**, a detector pad **3100** and a detector shell **3900**. A sensor cable **4400** attaches to the flex circuit assembly **2200**, which includes a flex circuit **2100**, an emitter assembly **500** and a detector assembly **2400**. The portion of the flex circuit assembly **2200** having the sensor cable **4400** attachment and emitter assembly **500** is housed by the emitter shell **3800** and emitter pad **3000**. The portion of the flex circuit assembly **2200** having the detector assembly **2400** is housed by the detector shell **3900** and detector pad **3100**. In particular, the detector assembly **2400** inserts into a shoe **3200**, and the shoe **3200** inserts into the detector pad **3100**. The emitter shell **3800** and detector shell **3900** are fastened by and rotate about hinge pins **410**, which insert through coils of a spring **3600**. The spring **3600** is held to the detector shell **3900** with a spring plate **3700**. A finger stop **450** attaches to the detector shell. In one embodiment, a silicon adhesive **420** is used to attach the pads **3000**, **3100** to the shells **3800**, **3900**, a silicon potting compound **430** is used to secure the emitter and detector assemblies **500**, **2400** within the pads **3000**, **3100**, and a cyanoacrylic adhesive **440** secures the sensor cable **4400** to the emitter shell **3800**.

A multiple wavelength sensor has been disclosed in detail in connection with various embodiments. These embodiments are disclosed by way of examples only and are not to limit the scope of the claims that follow. One of ordinary skill in art will appreciate many variations and modifications.

What is claimed is:

1. A physiological monitoring device comprising:
at least three LEDs recessed into a cavity, the at least three LEDs configured to emit light of at least three different wavelengths;
at least one detector configured to detect at least a portion of the light emitted from the at least three LEDs after at least a portion of the light has been attenuated by tissue, the at least one detector configured to output at least one signal responsive to the detected light;
a light block surrounding the at least one detector, the light block comprising a shoebox structure configured to recess the at least one detector into the shoebox structure, wherein the shoebox structure is at least partially formed of a black material, wherein a top of the shoebox structure includes only one opening through which light is configured to pass, the opening comprising an area smaller than a detection surface area of the at least one detector; and
a processor configured to receive and process one or more signals responsive to the outputted at least one signal and determine a physiological parameter of a user responsive to the one or more signals.
2. The device of claim 1, wherein the at least three LEDs comprises at least eight LEDs.
3. The device of claim 2, wherein the at least eight LEDs comprises at least two LEDs of the same wavelength.
4. The device of claim 1, wherein the at least three LEDs comprises at least twelve LEDs.
5. The device of claim 1, wherein at least two LEDs of the at least three LEDs are configured for concurrent activation.
6. The device of claim 1, wherein the at least one detector comprises at least two detectors.

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7. The device of claim 1, wherein the at least one detector comprises at least two detectors of different types.

8. The device of claim 1, wherein the opening provides an optical path from the tissue to the at least one detector.

9. The device of claim 1, wherein the opening provides an optical path from the at least three LEDs to the tissue.

10. A physiological monitoring device comprising:

at least three LEDs recessed into a cavity, the at least three LEDs configured to emit light of at least three different wavelengths;

at least one detector configured to detect at least a portion of the light emitted from the at least three LEDs after at least a portion of the light has been attenuated by tissue, the at least one detector configured to output at least one signal responsive to the detected light;

an electromagnetic interference shield positioned between the at least three LEDs and the at least one detector;

a light block surrounding the at least one detector, the light block at least partially formed of black materials, the light block comprising a base, four side walls and a top forming an enclosure, wherein the light block comprises a window, the window having an area smaller than a detection surface area of the at least one detector; and

a processor configured to receive and process one or more signals responsive to the outputted at least one signal and determine a physiological parameter of a user responsive to the one or more signals.

11. The device of claim 10, wherein the at least three LEDs comprises at least eight LEDs.

12. The device of claim 11, wherein the at least eight LEDs comprises at least two LEDs of the same wavelength.

13. The device of claim 10, wherein the at least three LEDs comprises at least twelve LEDs.

14. The device of claim 10, wherein at least two LEDs of the at least three LEDs are configured for concurrent activation.

15. The device of claim 10, wherein the at least one detector comprises at least two detectors.

16. The device of claim 10, wherein the at least one detector comprises at least two detectors of different types.

17. The device of claim 10, wherein the window provides an optical path from the tissue to the at least one detector.

18. The method of claim 10, wherein the window provides an optical path from the at least three LEDs to the tissue.

19. A method for determining a physiological parameter of a living patient, the method comprising:

positioning a sensor with respect to body tissue of a living patient, the sensor comprising at least three LEDs, at least one detector, and a light block at least partially surrounding the at least one detector, wherein a top of the light block comprises only one opening through which light is configured to pass;

activating the at least three LEDs such that at least three wavelengths of light are emitted from the at least three LEDs;

detecting, at the at least one detector, at least a portion of the light emitted from the at least three LEDs after at least a portion of the light has been attenuated by the body tissue and passed through the opening of the top of the light block, wherein the at least one detector outputs at least one signal responsive to the detected light; and

determining a physiological parameter of the living patient responsive to the outputted at least one signal.

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20. The method of claim 19, wherein an area of the opening is smaller than a detection surface area of the at least one detector.

21. The method of claim 19, wherein the light block is formed of black materials and further comprises a base, side walls, and a top forming an enclosure, and wherein the at least one detector is positioned in the enclosure. 5

22. The method of claim 19, wherein said activating the at least three LEDs comprises concurrently activating at least two LEDs of the at least three LEDs. 10

23. The method of claim 19, wherein the at least three LEDs comprises at least eight LEDs.

24. The method of claim 23, wherein the at least eight LEDs comprises at least two LEDs of the same wavelength.

25. The method of claim 19, wherein the at least three LEDs comprises at least twelve LEDs. 15

26. The method of claim 19, wherein the at least one detector comprises at least two detectors.

27. The method of claim 19, wherein the at least one detector comprises at least two detectors of different types. 20

28. The method of claim 19, wherein the at least a portion of the light passes through the opening after it interacts with the body tissue.

29. The method of claim 19, wherein the at least a portion of the light passes through the opening before it interacts with the body tissue. 25

* * * * *

EXHIBIT 18

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PTO/SB/17 (12-04v2)

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Effective on 12/08/2004.

Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).

**FEE TRANSMITTAL
For FY 2005**☐ Applicant claims small entity status. See 37 CFR 1.27**TOTAL AMOUNT OF PAYMENT** (\$) **200****Complete if Known**

Application Number

Filing Date

First Named Inventor

Ammar Al-Ali

Examiner Name

Art Unit

Attorney Docket No.

MLR.001PR

METHOD OF PAYMENT (check all that apply)☐ Check ☒ Credit Card ☐ Money Order ☐ None ☐ Other (please identify): _____☐ Deposit Account Deposit Account Number: _____ Deposit Account Name: _____

For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

☐ Charge fee(s) indicated below☐ Charge fee(s) indicated below, except for the filing fee☐ Charge any additional fee(s) or underpayments of fee(s) under 37 CFR 1.16 and 1.17☐ Credit any overpayments**WARNING:** Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.**FEE CALCULATION****1. BASIC FILING, SEARCH, AND EXAMINATION FEES**

Application Type	FILING FEES		SEARCH FEES		EXAMINATION FEES		Fees Paid (\$)
	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	
Utility	300	150	500	250	200	100	
Design	200	100	100	50	130	65	
Plant	200	100	300	150	160	80	
Reissue	300	150	500	250	600	300	
Provisional	200	100	0	0	0	0	200

2. EXCESS CLAIM FEES**Fee Description**

Each claim over 20 (including Reissues)

Fee (\$)**Small Entity Fee (\$)**

Each independent claim over 3 (including Reissues)

50

25

Multiple dependent claims

200

100

360

180

Total Claims**Extra Claims****Fee (\$)****Fee Paid (\$)**

- 20 or HP =

x

=

HP = highest number of total claims paid for, if greater than 20.

Indep. Claims**Extra Claims****Fee (\$)****Fee Paid (\$)**

- 3 or HP =

x

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3. APPLICATION SIZE FEE

If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

Total Sheets**Extra Sheets****Number of each additional 50 or fraction thereof****Fee (\$)****Fee Paid (\$)**

- 100 =

/ 50 =

(round up to a whole number) x

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4. OTHER FEE(S)

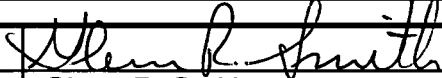
Non-English Specification, \$130 fee (no small entity discount)

Fees Paid (\$)

Other (e.g., late filing surcharge):

SUBMITTED BY

Signature

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38,308

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Glenn R. Smith

Date 03/01/2005

This collection of information is required by 37 CFR 1.136. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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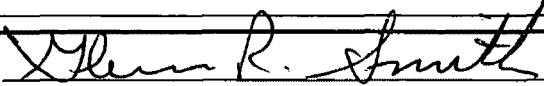
PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

Express Mail Label No. **ED 634185092 US**

INVENTOR(S)		
Given Name (first and middle [if any])	Family Name or Surname	Residence (City and either State or Foreign Country)
Ammar Mohamed	Al-Ali Diab	Tustin, CA Mission Viejo, CA
Additional inventors are being named on the <u>1</u> separately numbered sheets attached hereto		
TITLE OF THE INVENTION (500 characters max):		
MULTIPLE WAVELENGTH SENSOR		
Direct all correspondence to: CORRESPONDENCE ADDRESS		
<input checked="" type="checkbox"/> The address corresponding to Customer Number: 28222		
OR		
<input type="checkbox"/> Firm or Individual Name		
Address Law Office of Glenn R. Smith		
City 28626 Brookhill Road	State CA	Zip 92679-1163
Country USA	Telephone (949) 709-7164	Fax (949) 709-7164
ENCLOSED APPLICATION PARTS (check all that apply)		
<input type="checkbox"/> Application Data Sheet. See 37 CFR 1.76		
<input type="checkbox"/> CD(s), Number of CDs _____		
<input checked="" type="checkbox"/> Specification Number of Pages <u>20</u>		
<input type="checkbox"/> Other (specify) _____		
<input checked="" type="checkbox"/> Drawing(s) Number of Sheets <u>27</u>		
Application Size Fee: If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).		
METHOD OF PAYMENT OF FILING FEES AND APPLICATION SIZE FEE FOR THIS PROVISIONAL APPLICATION FOR PATENT		
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27.		TOTAL FEE AMOUNT (\$) 200
<input type="checkbox"/> A check or money order is enclosed to cover the filing fee and application size fee (if applicable).		
<input checked="" type="checkbox"/> Payment by credit card. Form PTO-2038 is attached		
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The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.		
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SIGNATURE



Date 03/01/2005

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REGISTRATION NO. 38,308

TELEPHONE (949) 709-7164

(if appropriate)

Docket Number: MLR.001PR

USE ONLY FOR FILING A PROVISIONAL APPLICATION FOR PATENT

This collection of information is required by 37 CFR 1.51. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 8 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Additional Page

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First Named Inventor	Ammar Al-Ali	Docket Number	MLR.001PR
INVENTOR(S)/APPLICANT(S)			
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Number 1 of 1

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MLR.001PR

PROVISIONAL PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	:	Ammar Al-Ali, et al.)	Group Art Unit Unknown
)	
Appl. No.	:)	
)	
Filed	:)	
)	
For	:	MULTIPLE WAVELENGTH SENSOR)	
)	
Examiner	:	Unknown)	
)	

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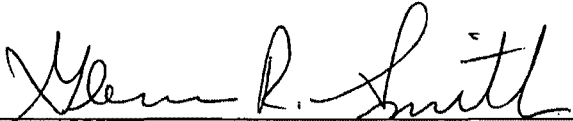
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Glenn R. Smith

MLR.001PR

PROVISIONAL PATENT

MULTIPLE WAVELENGTH SENSOR

INCORPORATION BY REFERENCE

[0001] The present application is related to the following copending U.S. applications: U.S. Pat. App. Ser. No. ###/###,###, titled "*Noninvasive Multi-Parameter Patient Monitor*," filed March 1, 2005; U.S. Pat. App. Ser. No. ###/###,###, titled "*Configurable Physiological Measurement System*," filed March 1, 2005, and U.S. Pat. App. Ser. No. ###/###,###, titled "*Physiological Parameter Confidence Measure*," filed March 1, 2005. The foregoing applications are incorporated by reference herein.

BACKGROUND OF THE INVENTION

[0002] Spectroscopy is a common technique for measuring the concentration of organic and some inorganic constituents of a solution. The theoretical basis of this technique is the Beer-Lambert law, which states that the concentration c_i of an absorbent in solution can be determined by the intensity of light transmitted through the solution, knowing the pathlength d_λ , the intensity of the incident light $I_{o,\lambda}$, and the extinction coefficient $\epsilon_{i,\lambda}$ at a particular wavelength λ . In generalized form, the Beer-Lambert law is expressed as:

$$I_\lambda = I_{o,\lambda} e^{-d_\lambda \cdot \mu_{a,\lambda}} \quad (1)$$

$$\mu_{a,\lambda} = \sum_{i=1}^n \epsilon_{i,\lambda} \cdot c_i \quad (2)$$

where $\mu_{a,\lambda}$ is the bulk absorption coefficient and represents the probability of absorption per unit length. The minimum number of discrete wavelengths that are required to solve EQS. 1-2 are the number of significant absorbers that are present in the solution.

[0003] A practical application of this technique is pulse oximetry, which utilizes a noninvasive sensor to measure oxygen saturation and pulse rate. The sensor has an emitter that transmits optical radiation of red and infrared wavelengths into a tissue site and a detector that responds to the intensity of the optical radiation after absorption by pulsatile arterial blood flowing within the tissue site. Based upon this response, a processor determines the relative concentrations of oxygenated hemoglobin (HbO₂) and deoxygenated hemoglobin (Hb) in the

blood so as to derive oxygen saturation, which can provide early detection of potentially hazardous decreases in a person's oxygen supply. A pulse oximetry sensor is described in U.S. Patent No. 6,088,607 entitled *Low Noise Optical Probe*; pulse oximetry signal processing is described in U.S. Patent Nos. 6,650,917 and 6,699,194 entitled *Signal Processing Apparatus* and *Signal Processing Apparatus and Method*, respectively; a pulse oximeter monitor is described in U.S. Patent No. 6,584,336 entitled *Univeral/Upgrading Pulse Oximeter*; all of which are assigned to Masimo Corporation, Irvine, CA and incorporated by reference herein.

SUMMARY OF THE INVENTION

[0004] There is a need to noninvasively measure multiple physiological parameters, other than, or in addition to, oxygen saturation and pulse rate. For example, hemoglobin species that are also significant under certain circumstances are carboxyhemoglobin (HbCO) and methemoglobin (MetHb). Other blood parameters that may be measured to provide important clinical information are total hemaglobin (Hbt) and blood glucose, to name a few.

BRIEF DESCRIPTION OF THE DRAWINGS

[0005] FIGS. 1A-B are a perspective view and a block diagram of a physiological measurement system utilizing a multiple wavelength sensor;

[0006] FIG. 2 is a perspective view of a multiple wavelength reusable sensor assembly;

[0007] FIG. 3 is an exploded perspective view of a multiple wavelength sensor;

[0008] FIG. 4 is a perspective view of an emitter assembly;

[0009] FIG. 5A-B are schematic diagrams of an emitter array and an LED pair;

[0010] FIGS. 6A-B are top and bottom component layout views of an emitter assembly;

[0011] FIG. 7 is a schematic diagram of an emitter assembly;

[0012] FIGS. 8A-B are a block diagram and a graph illustrating emitter equalization;

[0013] FIGS. 9A-B are top and side views of an encapsulated emitter assembly;

[0014] FIGS. 10A-C are perspective, detailed side and detailed layer views of an emitter substrate;

[0015] FIG. 11 is a partially-exploded perspective view of a flex circuit assembly;

[0016] FIG. 12 is an exploded perspective view of a flex circuit assembly emitter;

[0017] FIG. 13 is an exploded perspective view of a flex circuit assembly detector;

[0018] FIG. 14 is a top plan view of a flex circuit;

[0019] FIGS. 15A-H are perspective bottom, perspective top, bottom, back, top, side cross sectional, side, and front cross sectional views of an emitter pad;

[0020] FIGS. 16A-H are perspective bottom, perspective top, top, back, bottom, side cross sectional, side, and front cross sectional views of a detector pad;

[0021] FIGS. 17A-C are top, perspective and side views of a finger clip spring;

[0022] FIGS. 18A-D are top, back, bottom, and side views of a spring plate;

[0023] FIGS. 19A-D are front cross sectional, bottom, front and side cross sectional views of a top shell;

[0024] FIGS. 20A-D are back, top, front and side cross sectional views of a bottom shell;

[0025] FIGS. 21A-B are cross sectional and side cut away views of a multiple wavelength sensor cable; and

[0026] FIG. 22 is a block diagram of a sensor controller.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Overview

[0027] FIGS. 1A-B illustrate a physiological measurement system 10 having a monitor 100 and a multiple wavelength sensor assembly 200 with enhanced measurement capabilities as compared with conventional pulse oximetry. In particular, the multiple wavelength sensor assembly 200 allows the measurement of blood constituent and related parameters in addition to oxygen saturation and pulse rate. Alternatively, the multiple wavelength sensor assembly 200 allows the measurement of oxygen saturation and pulse rate with increased accuracy or robustness as compared with conventional pulse oximetry.

[0028] In one embodiment, the sensor assembly **200** is configured to plug into a monitor sensor port **110**. A monitor keyboard **160** provides control over operating modes and alarms, to name a few. A display **170** provides readouts of measured parameters, such as oxygen saturation and pulse rate, to name a few. In a particularly advantageous embodiment, the keyboard **160** can be pressed to change a display **170** readout from one parameter to another, such as from percentage oxygen saturation to percentage carboxyhemoglobin, and one parameter readout may be provided in a different color from another parameter readout.

[0029] As shown in FIG. **1B**, the sensor **300** houses emitters **500** responsive to drivers within a sensor controller **2200** so as to radiate light having a multiplicity of wavelengths. The sensor **300** also houses a detector **1310** that provides a detector signal responsive to the emitted light after absorption by pulsatile blood flow within a tissue site. The detector signal is filtered, amplified, sampled and digitized by the monitor front-end **130** and input to a DSP (digital signal processor) **140**, which also commands the sensor controller **2200**. The cable **2100** electrically communicates drive signals from the monitor's sensor controller **2200** to the sensor emitters **500** and a detector signal from the detector **1310** to the monitor front-end **130**. The monitor connector **210** plugs into the sensor port **110**.

[0030] In one embodiment, the monitor connector **210** houses an information element **212**, such as memory or other active or passive electrical component. In a particular embodiment, the information element **212** is an EPROM, or other programmable memory, or an EEPROM, or other reprogrammable memory, or both. In an alternative embodiment, the information element **212** is housed within the sensor **300**, or an information element **212** is housed within both the monitor connector **210** and the sensor **300**. A reader **120** inputs the information element **212** data to the DSP **140**.

[0031] In one embodiment, the DSP **140**, controller **2200**, front-end **130** and reader **120** are a portion of a processor board **101** incorporated into the monitor **100**. The processor board **101** communicates with a monitor CPU **150**, which processes keyboard **160** inputs and provides display **170** outputs, including physiological parameters calculated by the DSP **140**.

[0032] The sensor assembly **200** is described with respect to FIG. 2, below. The sensor **300** is described with respect to FIGS. 3-20, below. The cable **2100** is described with respect to FIG. 21. The sensor controller **2200** is described with respect to FIG. 22, below.

[0033] FIG. 2 illustrates a multiple wavelength sensor assembly **200** having a sensor **300** adapted to attach to a tissue site, a sensor cable **2100** and a monitor connector **210**. In one embodiment, the sensor **300** is a reusable finger clip adapted to transmit light through a finger, and the sensor cable **2100** and monitor connector **210** are integral to the sensor **300**, as shown. In alternative embodiments, the sensor **300** may be configured separately from the cable **2100** and connector **210**; the sensor **300** may utilize an adhesive attachment mechanism; the sensor **300** may be disposable or partially disposable and partially reusable (resposable); the sensor **300** may be configured to attach to various tissue sites other than a finger, such as a foot or an ear; and the sensor **300** may be configured as a reflectance device that attaches to a forehead or other tissue surface.

[0034] FIG. 3 illustrates a sensor **300** that attaches to a finger, reduces optical and EMI noise, connects to a multiple-wire sensor cable **2100** and houses a multiple wavelength emitter assembly **400**. In particular, pads **1500**, **1600** are contoured for a comfortable finger tip grip and are mechanically decoupled from shells **1900**, **2000** for increased flexibility. Further, the pads have flaps **1510**, **1610** (FIGS. 15-16) and a cage **1640** (FIG. 16A) that block ambient light and piped light from a detector assembly **1300**. A flex circuit assembly **1100** mechanically decouples the cable **2100** wires from the emitter assembly **400** and the detector assembly **1300** to reduce pad stiffness. A spring **1700** has a spring plate **1800** attachment to a bottom shell **2000** so that the sensor grip is evenly distributed along the finger. These and other features are described in detail below. Specifically, the sensor **300** is further described with respect to FIG. 3, below. The emitter assembly **400** is described with respect to FIGS. 4-10. The flexible circuit assembly **1100** is described with respect to FIGS. 11-14. The pads **1500**, **1600** are described with respect to FIGS. 15-16. The spring **1700** and spring plate **1800** are described with respect to FIGS. 17-18. The top and bottom shell **1900**, **2000** are described with respect to FIGS. 19-20 and the sensor cable **2100** is described with respect to FIGS. 21A-B.

[0035] As shown in FIG. 3, the sensor 300 has a top shell 1900, an emitter pad 1500, a flex circuit assembly 1100, a detector pad 1600 and a bottom shell 2000. A sensor cable 2100 attaches to the flex circuit assembly 1100, which includes an emitter assembly 400 and a detector assembly 1300. The portion of the flex circuit assembly 1100 having the sensor cable 2100 attachment and emitter assembly 400 is enclosed by the top shell 1900 and emitter pad 1500. The portion of the flex circuit assembly 1100 having the detector assembly 1300 is enclosed by the bottom shell 2000 and detector pad 1600. The top shell 1900 and bottom shell 2000 are fastened by and pivot about hinge pins 310, which insert through coils of a spring 1700. The spring 1700 is held to the bottom shell 2000 with a spring plate 1800. In one embodiment, a silicon adhesive 320 is used to attach the pads 1500, 1600 to the shells 1900, 2000, a silicon potting compound 330 is used to secure the emitter and detector assemblies 400, 1300 within the pads 1500, 1600, and a cyanoacrylic adhesive 340 secures the sensor cable 2100 to the top shell 1900.

Emitter Assembly

[0036] FIG. 4 illustrates one embodiment of an emitter assembly 400 having an emitter array 500, an optical filter 900 and a circuit board 1000. Various aspects of the emitter assembly 400 are described with respect to FIGS. 5-10, below. The emitter array 500 emits optical radiation having a multiplicity of nominal wavelengths of predetermined values, advantageously allowing multiple parameter measurements. The emitter array 500 has a multiplicity of LEDs (light emitting diodes) 501 (FIG. 5A) that are physically and electrically arrayed to facilitate drive control, equalization of intensities, and minimization of optical path differences at critical wavelengths, as described with respect to FIGS. 5-9, below. The optical filter 900 is advantageously configured to provide bulk intensity reduction for an LED group, as described with respect to FIGS. 8-9, below. The circuit board 1000 has internal thermal mass layers so as to provide a uniform, stable emitter array temperature. The circuit board 1000 also provides thermal coupling from the emitter array 500 to a thermistor 640 (FIGS. 6-9) located on an opposite circuit board side, as described with respect to FIGS. 10A-C, below. In this manner, a bulk temperature of the emitter array 500 may be measured so as to determine actual versus nominal LED wavelengths.

Emitter Array

[0037] FIG. 5A illustrates an emitter array 500 that provides both a physical and an electrical organization for a multiplicity of LEDs. The emitter array 500 has $n \times m$ LEDs 501 and requires $n + m$ drive lines 512, 522, where n and m integers greater than one. Electrically, this configuration minimizes the number of drive lines required to activate the LEDs 501 while preserving flexibility to selectively activate individual LEDs 501 in any sequence and multiple LEDs 501 simultaneously. The electrical configuration also facilitates setting individual LED currents to control intensity and measuring and limiting array current so as to control power dissipation. The emitter array 500 is also physically configured as n rows 510 and m columns 520, which facilitates clustering LEDs 501 according to wavelength so as to minimize path length variations. This physical configuration also facilitates equalization of LED intensities as described below with respect to FIGS. 9A-B.

[0038] As shown in FIG. 5A, one embodiment of an emitter array 500 comprises up to sixteen LEDs 501 configured as four rows 510 and four columns 520. Each of the four row drive lines 512 provide a common anode connection to four LEDs 501, and each of the four column drive lines 522 provide a common cathode connection to four LEDs 501. Thus, the sixteen LEDs 501 are advantageously driven with only eight wires, including four anode drive lines 512 and four cathode drive lines 522. This compares favorably to conventional common anode or cathode LED configurations, which require separate drive lines for each anode or cathode. In a particular embodiment, the emitter array 500 is partially populated with eight LEDs having nominal wavelengths as shown in TABLE 1. Further, LEDs having wavelengths in the range of 610-630 nm are grouped together. This particular emitter array 500 is adapted to a physiological measurement system 10 (FIGS. 1A-B) for measuring H_bCO in addition to S_pO_2 and pulse rate.

LED	λ	Row	Col
D1	630	1	1
D2	620	1	2
D3	610	1	3
D4		1	4
D5	700	2	1
D6	730	2	2
D7	660	2	3
D8	805	2	4
D9		3	1
D10		3	2
D11		3	3
D12	905	3	4
D13		4	1
D14		4	2
D15		4	3
D16		4	4

TABLE 1: Nominal LED Wavelengths

[0039] Also shown in FIG. 5A, row drivers 2301 and column drivers 2202 located in the monitor 100 selectively activate the LEDs 501. In particular, row and column drivers 2201, 2202 function together as switches to Vcc and a current sink, respectively, to activate LEDs and as switches to ground and Vcc, respectively, to deactivate LEDs. This push-pull drive configuration advantageously prevents parasitic current flow in deactivated LEDs. In a particular embodiment, only one row driver 2201 is switched to Vcc at a time. One to four column drivers 2202, however, can be simultaneously switched to a current sink so as to simultaneously activate multiple LEDs within a particular row. Activation of two or more LEDs of the same wavelength facilitates intensity equalization, as described with respect to FIGS. 9A-B, below. LED drivers are described in further detail with respect to FIG. 22, below. FIG. 5B illustrates that an array drive, as described above, can also be configured to drive a conventional pulse oximetry sensor, such as the back-to-back IR and red LEDs 560 and corresponding information element resistor 570 as shown.

[0040] FIGS. 6A-B illustrate the physical layout of an emitter assembly 400 showing the mounted emitter array 500, described above. The emitter assembly 400 has a component side 601, a solder side 602, a component end 605 and a connector end 606. Alignment notches 610 are disposed between the ends 605, 606. As shown in FIG. 6A, the component end 605 of the component side 601 has LEDs 501 mounted to component pads (not visible) and wire bond pads 620. The connector end 606 of the component side 601 has a connector 630 and associated connector pads 632. The LEDs 501 are physically and electrically connected to the component pads 1050 (FIG. 10A) and also wire bonded to the wire bond pads 620, as described with respect to FIG. 7, below. Circuit board layers have traces that electrically connect the wire bond pads 620 and component pads 1050 (FIG. 10A) to the connector 630, as described with respect to FIG. 7, below. As shown in FIGS. 6B, the solder side 602 has a thermistor 640 at the component end 605 and the connector 630 with connector pads 634 at the connector end 606. Plated thru holes electrically connect the connector pads 632, 634 on the component and solder sides 601, 602, respectively. Circuit board layers have traces that electrically connect the thermistor 640 to the connector 630, as described with respect to FIGS. 7, below.

[0041] FIG. 7 illustrates the electrical layout of an emitter assembly 400. A portion of the LED chips 501, including D1-D4 and D13-D16 have cathodes physically and electrically connected to component pads 1050 (FIG. 10A) and corresponding anodes wire bonded to wire bond pads 620. Another portion of the LED chips 501, including D5-D8 and D9-D12, have anodes physically and electrically connected to component pads 1050 (FIG. 10A) and corresponding cathodes wire bonded to wire bond pads 620. The connector 630 has row pinouts J21-J24, column pinouts J31-J34 and thermistor pinouts J40-J41 for the LEDs 501 and thermistor 640, which correspond to the connector pads 632, 634 (FIGS. 6A-B).

Optical Filters

[0042] FIGS. 8A-B generally illustrate emitter equalization. FIG. 8A illustrates a physiological measurement system 10 having array drivers 2201-2202, an emitter array 500, an optical filter 900, a detector 1310 and a processor front-end 130 operating on a tissue site 20. FIG. 8B shows tissue absorption versus wavelength illustrating that the significant

absorbers, Hb and HbO₂, attenuate red wavelengths significantly more than IR wavelengths. It is desirable to provide an ADC (analog-to-digital converter) input signal that falls well within the dynamic range limits of the ADC across the entire emitter spectrum. This can be achieved, in part, by adjusting array drive currents **2201**, **2202** and front-end amplification **130** so as to compensate for tissue **20** absorption. To a more limited extent, this can be achieved by selection of particular emitter array **500** and detector **1310** components, e.g. LEDs having higher output intensities or detectors having higher sensitivities at red wavelengths. Signal demodulation constraints limit the amount of variation of front-end amplification **130** versus wavelength. As such, in one embodiment, it is desirable to equalize emitter intensity so as to provide a relatively constant intensity versus wavelength at the detector **1310**, i.e. emerging from the tissue site **20**. This is difficult to achieve solely by varying the output current of array drivers **2101-2102**. Advantageously, an optical filter **900** can provide such equalization.

[0043] As shown in FIGS. **8A-B**, an optical filter **900** ideally has an attenuation versus wavelength characteristic **820** that is the inverse of tissue absorption **810**, i.e. attenuating IR wavelengths proportionately greater than red wavelengths. In one embodiment, corresponding to TABLE 1 above, the 610-630 nm LEDs are optically unfiltered (unattenuated) and the remaining 660-905 nm LEDs are optically filtered (attenuated). In a particular embodiment, the filtered LED intensities are attenuated in the range of 50%. In an alternative embodiment, multiple LEDs of the same wavelength can be simultaneously activated so as to boost tissue attenuated wavelengths or inherently weak output LEDs, as described below.

[0044] FIGS. **9A-B** illustrate an optical filter **900** for an emitter assembly **400**. LEDs within the emitter array **500** may be grouped according to output intensity or wavelength or both. Such a grouping facilitates equalization of LED intensity across the array. In particular, relatively low tissue absorption and/or relatively high output intensity LEDs can be grouped together under a relatively high attenuation optical filter. Likewise, relatively low tissue absorption and/or relatively low output intensity LEDs can be grouped together without an optical filter or under a relatively low or negligible attenuation optical filter. Further, high tissue absorption and/or low intensity LEDs can be grouped within the

same row with one or more LEDs of the same wavelength being simultaneously activated, as described with respect to FIG. 5, above. In general, there can be any number of LED groups and any number of LEDs within a group. There can also be any number of optical filters corresponding to the groups having a range of attenuation, including no optical filter and/or a "clear" filter having negligible attenuation.

[0045] As shown in FIGS. 9A-B, a filtering media may be advantageously added to an encapsulant that functions both to cover and protect LED chips and bonding wires and as an optical filter 900. In one embodiment, a filtering media 910 encapsulates a select group of LEDs and a clear media 920 encapsulates the entire array 500 and the filtering media 910. In a particular embodiment, five LEDs nominally emitting at 660-905 nm are encapsulated with both a filtering media 910 and an overlying clear media 920, and three LEDs nominally emitting at 610-630 nm are only encapsulated with the clear media 920. In an alternative embodiment, individual LEDs may be singly or multiply encapsulated according to tissue absorption and/or output intensity. In other alternative embodiments, filtering media may be separately attachable optical filters or a combination of encapsulants and separately attachable optical filters. In a particular embodiment, the emitter assembly 400 (FIGS. 6A-B) has one or more notches along each side proximate the component end 605 (FIGS. 6A-B) for retaining one or more clip-on optical filters.

Circuit Board

[0046] FIGS. 10A-C illustrate a circuit board 1000 for an emitter assembly 400 (FIG. 4) described above with respect to FIGS. 4-9. The circuit board 1000 has a component side 601, a solder side 602 and multiple layers 1011-1016. The circuit board 1000 is configured to provide thermal conductivity between an emitter array 500 (FIG. 6A) on the component side 601 and a thermistor 640 (FIG. 6B) on the solder side 602. In this manner, the resistance of the thermistor 640 can be measured in order to determine the bulk temperature of the LEDs 501 (FIG. 6A). The circuit board 1000 is also configured with a relatively significant thermal mass, stabilizing and normalizing the circuit board temperature across the LEDs so that the circuit board temperature measured by the thermistor is representative of the individual LED temperatures. As a result, the actual wavelength λ_a of a particular LED can be determined as some function:

$$\lambda_a = f(T_b, I) \quad (3)$$

where T_b is a bulk temperature of the emitter array according to the thermistor **640** (FIGS. 6-7), and I is the particular LED drive current, as determined by the sensor controller **2200** (FIG. 22), described below.

[0047] As shown in FIGS. 10B-C, the circuit board **1000** has a component layer **1011**, inner layers **1012-1015** and a solder layer **1016**. The inner layers **1012-1015**, e.g. inner layer **1012** (FIG. 10C), have substantial metallized areas **1001** that provide the thermal mass to stabilize the circuit board **1000** across the emitter array **500**. The metallized areas **1001** also function to interconnect component pads **1050** and wire bond pads **620** (FIG. 6A) to the connector **630**.

Flex Circuit Assembly

[0048] FIG. 11 illustrates a flex circuit assembly **1100** having a flex circuit **1400**, an emitter assembly **400** and a detector assembly **1300**, which is configured to terminate the sensor end of a sensor cable **2100**. The flex circuit assembly **1100** advantageously provides a structure that electrically connects yet mechanically isolates the sensor cable **2100** the emitter assembly **400** and the detector assembly **1300**. As a result, the mechanical stiffness of the sensor cable **2100** is not translated to the sensor pads **1500**, **1600** (FIG. 3), allowing a comfortable finger attachment for the sensor **200** (FIG. 1A). In particular, the emitter assembly **400** and detector assembly **1300** are mounted to opposite ends **1410**, **1420** of an elongated flex circuit **1400**. The sensor cable **2100** is mounted to a cable connector **1430** extending from a middle portion of the flex circuit **1400**. Detector wires **2170** are shielded at the flex circuit junction by a fold-over conductive ink flap **1434**, which is connected to a cable inner shield **2150**. The emitter portion **1200** of flex circuit assembly **1100** is described in further detail with respect to FIG. 12. The detector assembly **1300** is described with respect to FIG. 13. The flex circuit **1400** is described in further detail with respect to FIG. 14, and the sensor cable **2100** is described with respect to FIGS. 21A-B, below.

[0049] FIG. 12 illustrates the emitter portion **1200** of the flex circuit assembly **1100** (FIG. 11) having the emitter assembly **400**. The emitter assembly connector **630** is attached to the emitter end **1410** of the flex circuit **1400**. In particular, reflow solder **1210**

connects thru hole pads **632**, **634** of the emitter assembly **400** to corresponding emitter pads **1412** of the flex circuit **1400**.

[0050] FIG. 13 illustrates a detector assembly **1300** including a detector **1310**, Kapton tape **1320**, copper mesh tape **1330**, an EMI shield **1340** and foil **1350**. The detector **1310** is soldered **1360** chip side down to detector pads **1420** of the flex circuit **1400**. The detector solder joint and detector pads **1420** are wrapped with the Kapton tape **1320**. EMI shield tabs **1342** are folded onto the detector pads **1420** and soldered. The EMI shield walls are folded around the detector **1310** and the remaining tabs **1342** are soldered to the back of the EMI shield **1340**. The copper mesh tape **1330** is cut to size and the shielded detector and flex circuit solder joint are wrapped with the tape **1330**. The foil **1350** is cut to size with a predetermined aperture **1352**. The foil **1350** is wrapped around shielded detector with the foil side in and the aperture **1352** is aligned with the EMI shield grid **1344**.

[0051] FIG. 14 illustrates a sensor flex circuit **1400** having an emitter end **1410**, a detector end **1420**, an elongated interconnect **1442**, **1444** between the ends **1410**, **1420** and a cable connector **1430** extending from the interconnect **1442**, **1444**. The emitter end **1410** forms a "head" having emitter solder pads **1412** for attaching the emitter assembly **400** (FIG. 12) and mounting ears **1414** for attaching to the emitter finger pad **1500** (FIG. 15B), as described below. The detector end **1420** has detector solder pads **1422** for attaching the detector **1310** (FIG. 13). The interconnect **1442** between the emitter pads **1412** and the cable connector **1430** forms a "neck," and the interconnect **1444** between the detector pads **1422** and the cable connector **1430** forms a "tail." The cable connector **1430** forms "wings" that extend from the interconnect **1442**, **1444** between the neck **1442** and tail **1444**. A conductive ink flap **1434** connects to the cable inner shield **2150** (FIGS. 21A-B) and folds over to shield the detector wires **2170** (FIGS. 21A-B) soldered to the detector wire pads **1436**. The outer wire pads **1438** connect to the remaining cable wires **2130** (FIGS. 21A-B). The flex circuit **1400** has top coverlay, top ink, inner coverlay, trace, trace base, bottom ink and bottom coverlay layers.

[0052] The flex circuit **1400** advantageously provides a connection between a multiple wire sensor cable **2100** (FIGS. 21A-B), a multiple wavelength emitter assembly **400** (FIG. 4) and a detector assembly **1300** (FIG. 13) without rendering the emitter and detector

assemblies unwieldy and stiff. In particular, the wings **1430** provide a relatively large solder pad area **1432** that is narrowed at the neck **1442** and tail **1444** to mechanically isolate the cable **2100** (FIGS. **21A-B**) from the remainder of the flex circuit **1400**. Further, the neck **1442** is folded (see FIG. **3**) for installation in the emitter finger pad **1500** (FIGS. **15A-H**) and acts as a flexible spring to further mechanically isolate the cable **2100** (FIGS. **21A-B**) from the emitter assembly **400** (FIG. **3**). The tail **1444** provides an integrated connectivity path between the detector assembly **1300** (FIG. **13**) mounted in the detector finger pad **1600** (FIGS. **16A-H**) and the cable connector **1430** mounted in the opposite emitter finger pad **1500** (FIGS. **15A-B**).

Sensor Pads

[0053] FIGS. **15A-H** illustrate an emitter pad **1500** having top flaps **1510**, an emitter window **1520**, mounting pins **1530**, an emitter assembly cavity **1540**, isolation notches **1550**, a flex circuit notch **1570** and a cable notch **1580**. The top flaps **1510** overlap with bottom flaps **1610** (FIGS. **16A-H**) to block ambient light. The emitter window **1520** provides an optical path from the emitter array **500** (FIG. **5**) to a tissue site. The mounting pins **1530** accommodate apertures in the flex circuit mounting ears **1414** (FIG. **14**), and the cavity **1540** accommodates the emitter assembly **400** (FIG. **4**). Isolation notches **1550** mechanically decouple the shell attachment from the remainder of the emitter pad **1500**. The flex circuit notch **1570** accommodates the flex circuit tail **1444** (FIG. **14**) routed to the detector pad **1600** (FIGS. **16A-H**). The cable notch **1580** accommodates the sensor cable **2100** (FIGS. **21A-B**).

[0054] FIGS. **16A-H** illustrate a detector pad **1600** having bottom flaps **1610**, a detector window **1620**, a finger contour **1630**, a detector assembly cavity **1640**, isolation notches **1650**, a flex circuit notch **1670** and spring leg notches **1680**. The bottom flaps **1610** overlap with top flaps **1510** (FIGS. **15A-H**) to block ambient light. The detector window **1620** provides an optical path from a tissue site to the detector **1310** (FIG. **13**). The finger contour **1630** provides a comfortable finger positioning mechanism for the sensor **200** (FIG. **1A**), which has an inward taper and rise toward a finger tip. The cavity **1640** accommodates the detector assembly **1300** (FIG. **13**). Isolation notches **1650** mechanically decouple the

attachment points **1660** from the remainder of the detector pad **1600**. The flex circuit notch **1670** accommodates the flex circuit tail **1444** routed from the emitter pad **1500** (FIGS. **15A-H**). The spring leg notches **1580** accommodate the spring legs **1730** (FIGS. **17A-C**).

Sensor Finger Clip

[0055] FIGS. **17A-C** illustrate a finger clip spring **1700** having coils **1710**, a top shell leg **1720** and bottom shell legs **1730**. The spring **1700** provides tension to the top and bottom shells **1900**, **2000** (FIGS. **19-20**) so that the sensor **200** (FIG. **1A**) remains attached to an inserted finger tip. The top shell leg **1720** rests against the top shell **1900** (FIGS. **19A-D**) proximate a grip **1920** (FIGS. **19A-D**). The bottom shell legs **1730** extend along the bottom shell **2000** (FIGS. **20A-D**) to a spring plate **1800** (FIGS. **18A-D**) attachment point. The spring plate **1800** (FIGS. **18A-D**) is secured to the bottom shell distal the grip **2020** (FIGS. **20A-D**), advantageously creating a pivot point on an inserted finger and allowing the shell hinge **1910**, **2010** (FIGS. **19-20**) to expand so as to distribute finger clip force along the inserted finger. The coil **1710** is secured by hinge pins **310** (FIG. **3**) and is configured to wind as the finger clip is opened, reducing its diameter and stress accordingly.

[0056] FIGS. **18A-D** illustrate a spring plate **1800** having attachment apertures **1810**, spring leg slots **1820**, and a shelf **1830**. The attachment apertures **1810** accept corresponding shell posts **2030** (FIGS. **20A-D**) so as to secure the spring plate **1800** to the bottom shell **2000** (FIG. **20A-D**). Spring legs **1730** (FIG. **17A-C**) are secured within the slots **1820** and held in place by the shelf **1830**.

[0057] FIGS. **19-20** illustrate the top and bottom shells **1900**, **2000**, respectively, having hinges **1910**, **2010** and grips **1920**, **2020**. Hinge apertures **1912**, **2012** accept hinge pins **310** (FIG. **3**) so as to create a finger clip. The bottom shell hinge aperture **2012** is elongated, allowing the hinge to expand to accommodate a finger.

Sensor Cable

[0058] FIGS. **21A-B** illustrate a sensor cable **2100** having an outer jacket **2110**, an outer shield **2120**, multiple outer wires **2130**, an inner jacket **2140**, an inner shield **2150**, a conductive polymer **2160** and an inner twisted wire pair **2170**. The outer wires **2130** are advantageously configured to compactly carry multiple drive signals to the emitter array **500**

(FIG. 5). In one embodiment, there are twelve outer wires **2130** corresponding to four anode drive signals **512** (FIG. 5), four cathode drive signals **522** (FIG. 5), two thermistor **640** (FIG. 6B) pinouts and two spares. The inner twisted wire pair **2170** corresponds to the detector **1310** (FIG. 13) signal and is extruded within the conductive polymer **2160** so as to reduce triboelectric noise. The shields **2120**, **2150** and the twisted pair **2170** boost EMI and crosstalk immunity for the detector signal.

Sensor Controller

[0059] FIG. 22 illustrates a sensor controller **2200** located in the monitor **100** (FIGS. 1A-B) and configured to provide anode drive signals **2201** and cathode drive signals **2202** to the emitter array **500** (FIG. 5). The DSP (digital signal processor) **140**, which performs signal processing functions for the monitor, also provides commands to the sensor controller **2200**. These commands determine drive signal **2201**, **2202** levels and timing. The sensor controller **2200** has a command register **2210**, an anode selector **2220**, anode drivers **2230**, current DACs (digital-to-analog converters) **2240**, a current multiplexer **2250**, cathode drivers **2260**, a current meter **2270** and a current limiter **2280**. The command register **2210** provides control signals responsive to the DSP **140** commands. In one embodiment, the command register **2210** is a shift register that loads serial command data **142** from the DSP **140** and synchronously sets output bits that select or enable various functions within the sensor controller **2200**, as described below.

[0060] As shown in FIG. 22, the anode selector **2220** is responsive to anode select **2215** inputs from the command register **2210** that determine which emitter array row **510** (FIG. 5) is active. Accordingly, the anode selector **2220** sets one of the anode on **2222** outputs to the anode drivers **2230**, which pulls up to Vcc one of the anode **2201** outputs to the emitter array **500** (FIG. 5).

[0061] Also shown in FIG. 22, the current DACs **2240** are responsive to command register data **2219** that determines the currents through each emitter array column **520** (FIG. 5). In one embodiment, there are four, 12-bit DACs associated with each emitter array column **520** (FIG. 5), sixteen DACs in total. That is, there are four DAC outputs **2242** associated with each emitter array column **520** (FIG. 5) corresponding to the currents

associated with each row **510** (FIG. 5) along that column **520** (FIG. 5). In a particular embodiment, all sixteen DACs **2240** are organized as a single shift register, and the command register **2210** serially clocks DAC data **2219** into the DACs **2240**. A current multiplexer **2250** is responsive to cathode on **2218** inputs from the command register **2210** and anode on **2222** inputs from the anode selector **2220** so as to convert the appropriate DAC outputs **2242** to current set **2252** inputs to the cathode drivers **2260**. The cathode drivers **2260** are responsive to the current set **2252** inputs to pull down to ground one to four of the cathode **2202** outputs to the emitter array **500** (FIG. 5).

[0062] The current meter **2270** outputs a current measure **2272** that indicates the total LED current driving the emitter array **500** (FIG. 5). The current limiter **2280** is responsive to the current measure **2272** and limits specified by the command register **2210** so as to prevent excessive power dissipation by the emitter array **500** (FIG. 5). The current limiter **2280** provides an enable **2282** output to the anode selector **2220**. A hi limit **2212** input specifies the higher of two preset current limits. The current limiter **2280** latches the enable **2282** output in an off condition when the current limit is exceeded, disabling the anode selector **2220**. A trip reset **2214** input resets the enable **2282** output to re-enable the anode selector **2220**.

[0063] A multiple wavelength sensor has been disclosed in detail in connection with various embodiments. These embodiments are disclosed by way of examples only and are not to limit the scope of the claims that follow. One of ordinary skill in art will appreciate many variations and modifications.

WHAT IS CLAIMED IS:

1. A physiological sensor comprising:
an array of LEDs having n rows by m columns, where n and m are both integers greater than one,
said array capable of transmitting light having a multiplicity of wavelengths into a tissue site; and
a detector capable of receiving said light after tissue absorption;
2. The physiological sensor according to claim 1 further comprising:
a plurality of row drivers; and
a plurality of column drivers,
each of said LEDs having an anode in common with one of said row drivers and a cathode in common with one of said column drivers so that activating one of said row drivers and one of said column drivers activates a unique one of said LEDs.
3. A physiological sensor comprising:
a multiplicity of LEDs adapted to emit optical radiation having a multiplicity of wavelengths;
a substrate having a first side and a second side, said LEDs mounted to said first side;
a thermistor mounted to said second side; and
a thermal mass disposed between said first and second sides configured to provide a thermally conductive path between said LEDs and said thermistor and to stabilize a bulk temperature of said LEDs so that said thermistor is responsive to said bulk temperature.

4. A physiological sensor comprising:
a multiplicity of LEDs configured to emit optical radiation having a multiplicity of wavelengths;
a detector capable of receiving said optical radiation after tissue absorption;
a first portion of said LEDs configured to emit a first plurality of wavelengths;
a second portion of said LEDs configured to emit a second plurality of wavelengths, said first plurality of wavelengths each subject to tissue absorption that is substantially greater than each of said second plurality of wavelengths,
an optical filter applied to said second portion of said LEDs so as to generally equalize the optical radiation intensity at said detector for said first and second plurality of wavelengths.

5. The physiological sensor according to claim 4 wherein said first plurality of wavelengths is less than about 640 nm and said second plurality of wavelengths is greater than about 640 nm.

6. A physiological sensor method comprising the steps of:
providing a multiplicity of LEDs configured to transmit optical radiation having a multiplicity of wavelengths into a tissue site having pulsatile blood flow;
identifying a plurality of said LEDs configured to transmit optical radiation at a subset of said wavelengths, said subset configured to be substantially absorbed by a selected blood constituent; and
adjacently locating said plurality of said LEDs so as to minimize path length differences through said tissue site for optical radiation at said subset of said wavelengths.

7. A physiological sensor comprising:
a top shell;
a bottom shell,
said top shell and said bottom shell pivotably connected and urged together so as to be removably attachable to a finger tip;
an emitter pad fixedly retained by said top shell;
an emitter assembly mounted within said emitter pad and adapted to transmit light having a multiplicity of wavelengths into said finger tip;
a detector pad fixedly retained by said bottom shell;
a detector assembly mounted within said detector pad and adapted to receive said light after absorption by said finger tip; and
a contour defined along said detector pad configured to position said finger tip over said detector.

Title: Multiple Wavelength Sensor
Applicant: Ahmad Al-Ali et al.
Docket No.: MLR.001PR
Attorney: Glenn Smith (949) 709-7164
Page: 1 of 27

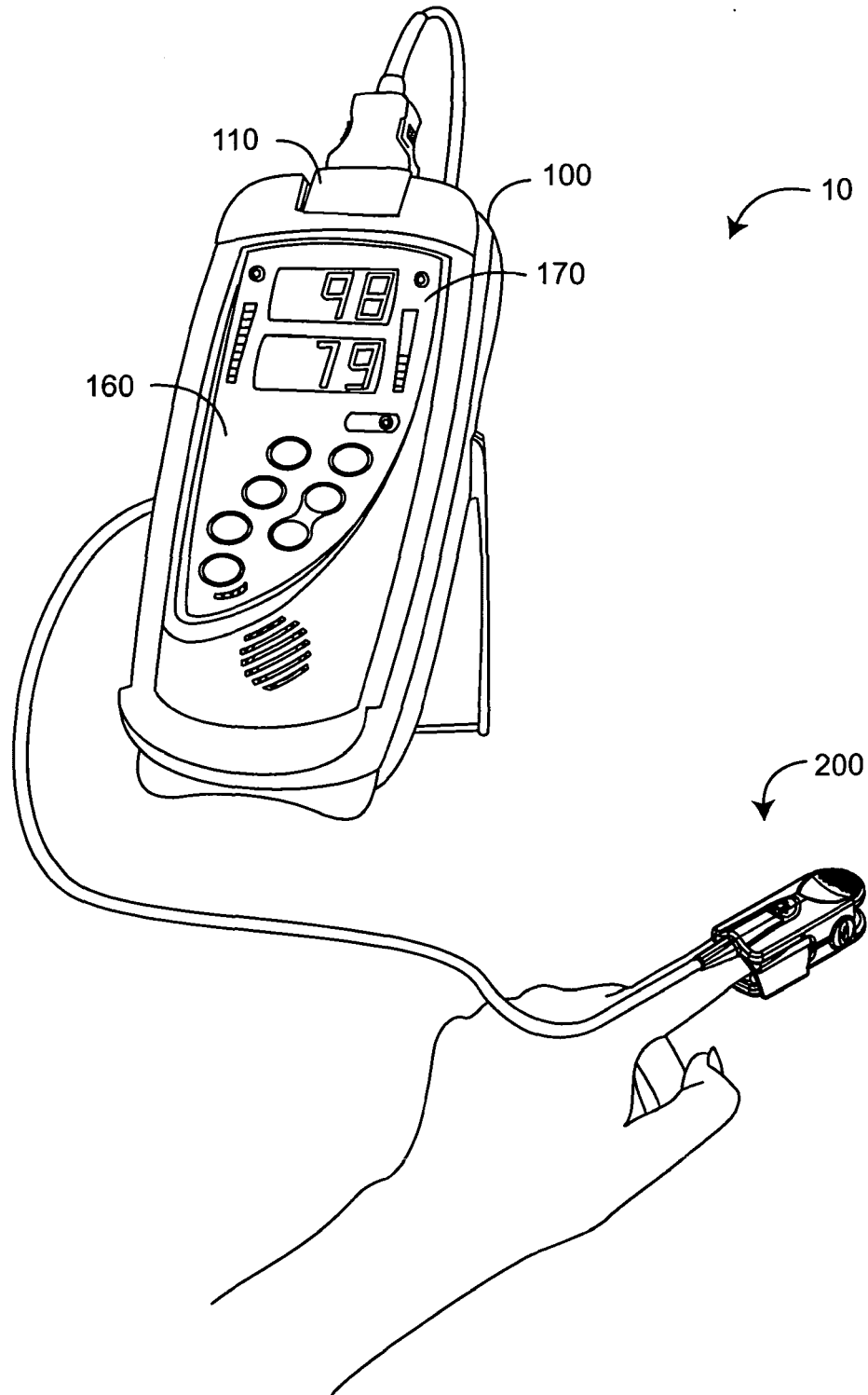


FIG. 1A

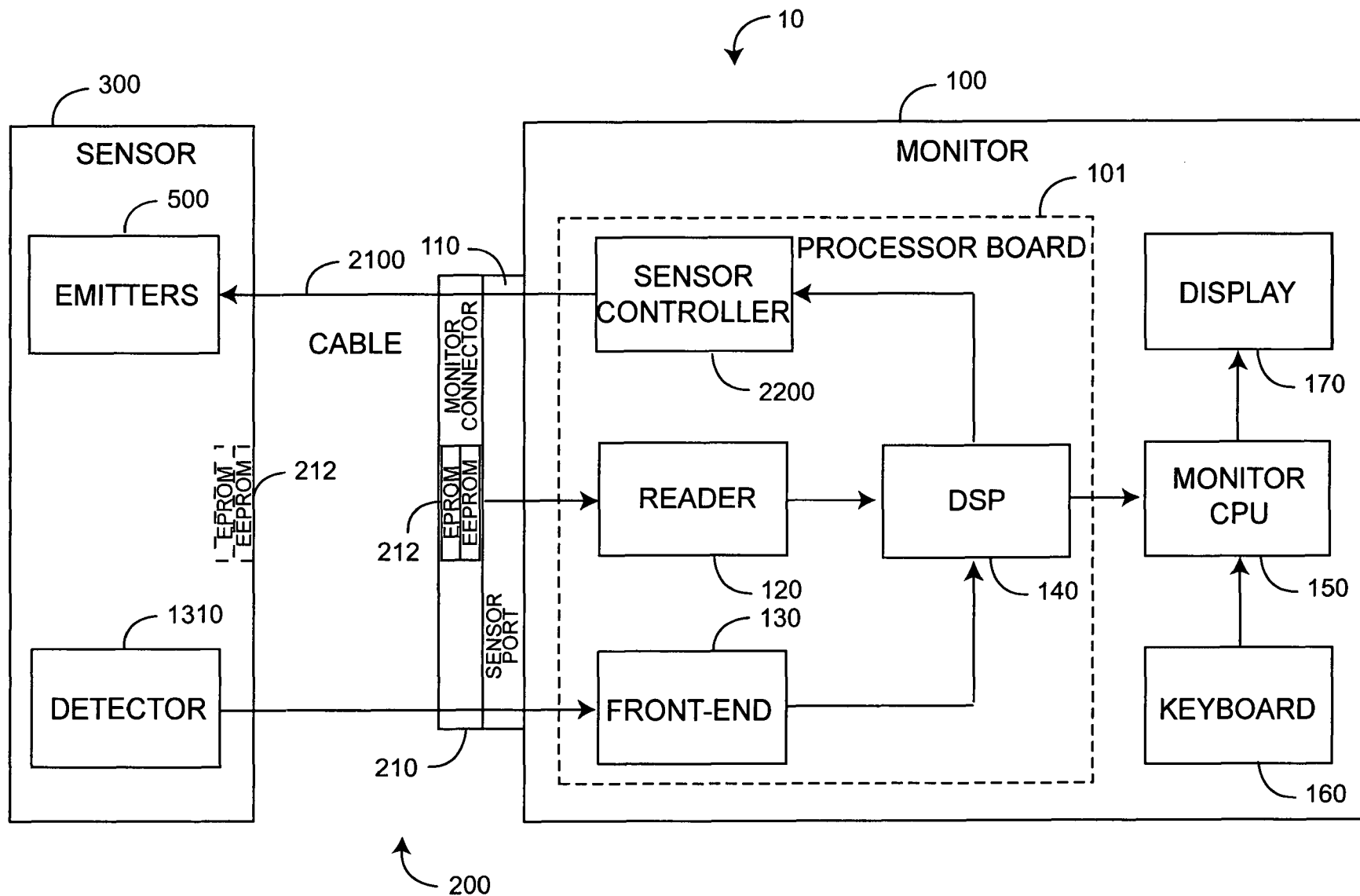


FIG. 1B

Title: Multiple Wavelength Sensor
Applicant: Ammar Al-Ali et al.
Docket No.: MLR.001PR
Attorney: Glenn Smith (949) 709-7164
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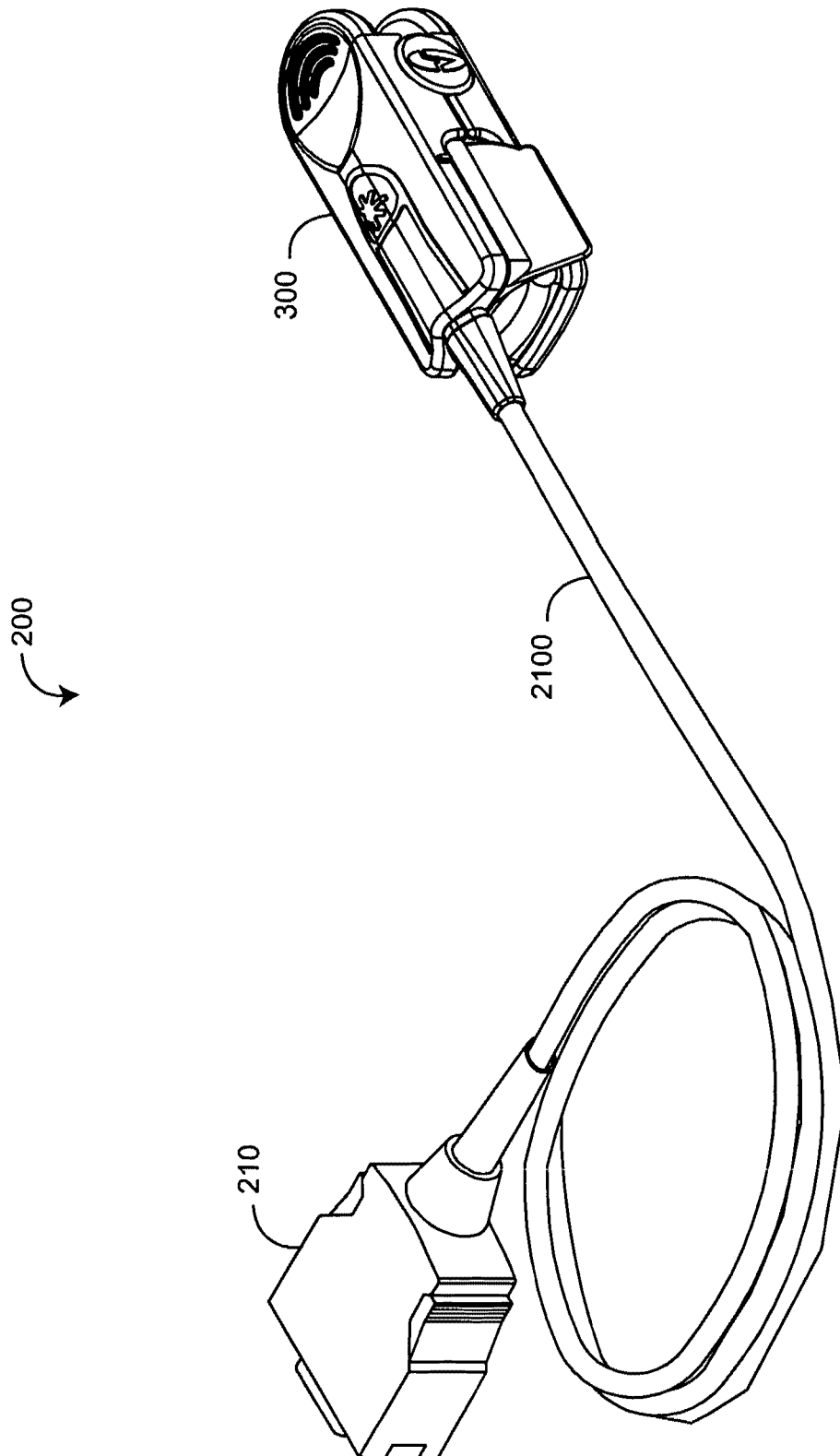


FIG. 2

Title: Multiple Wavelength Sensor
 Applicant: Ammar Al Ali et al.
 Docket No.: MLR.001PR
 Attorney: Glenn Smith (949) 709-7164
 Page: 4 of 27

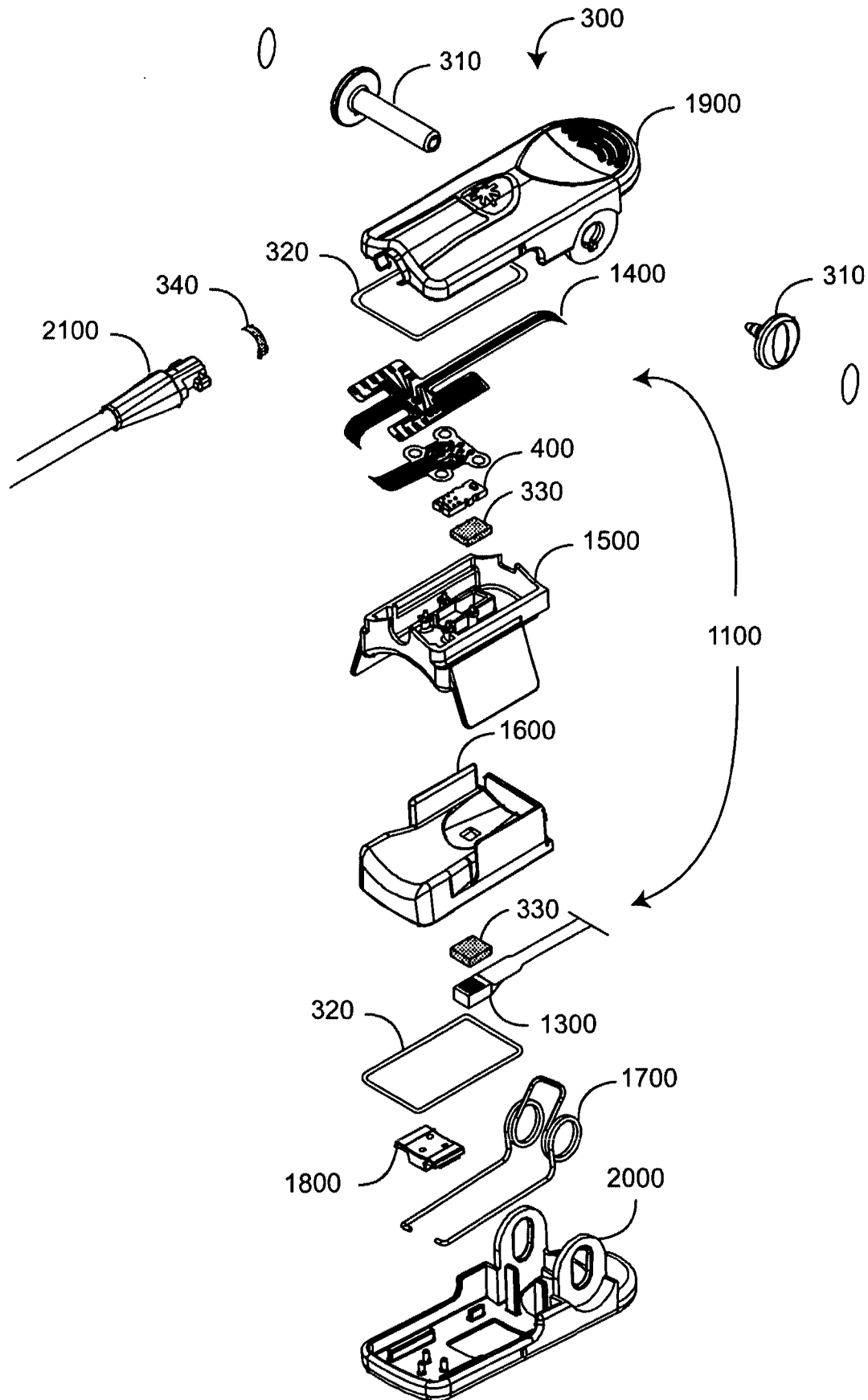


FIG. 3

Title: Multiple Wavelength Sensor
Applicant: Ammar Al Ali et al.
Docket No.: MLR.001PR
Attorney: Glenn Smith (949) 709-7164
Page: 5 of 27

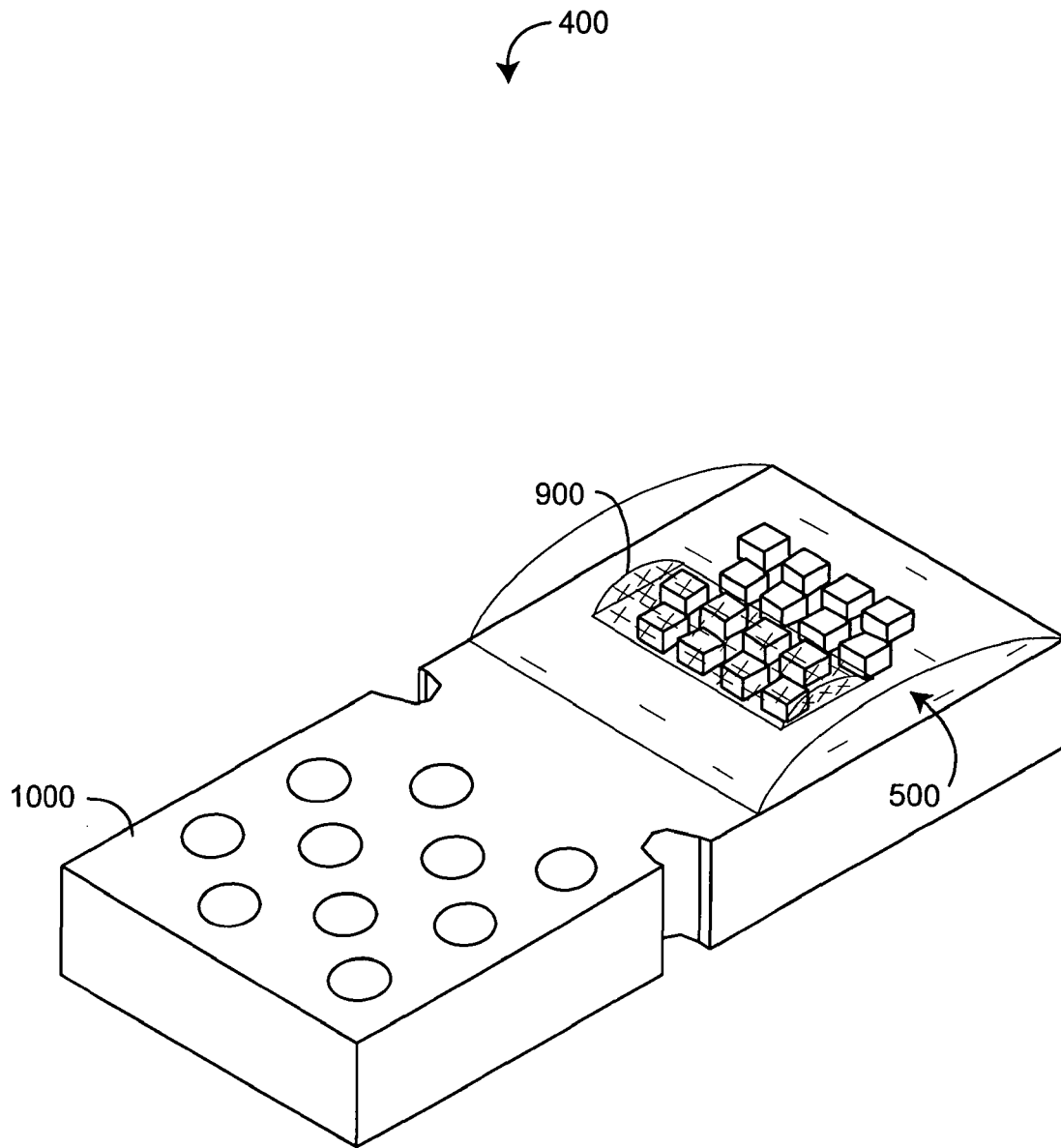


FIG. 4

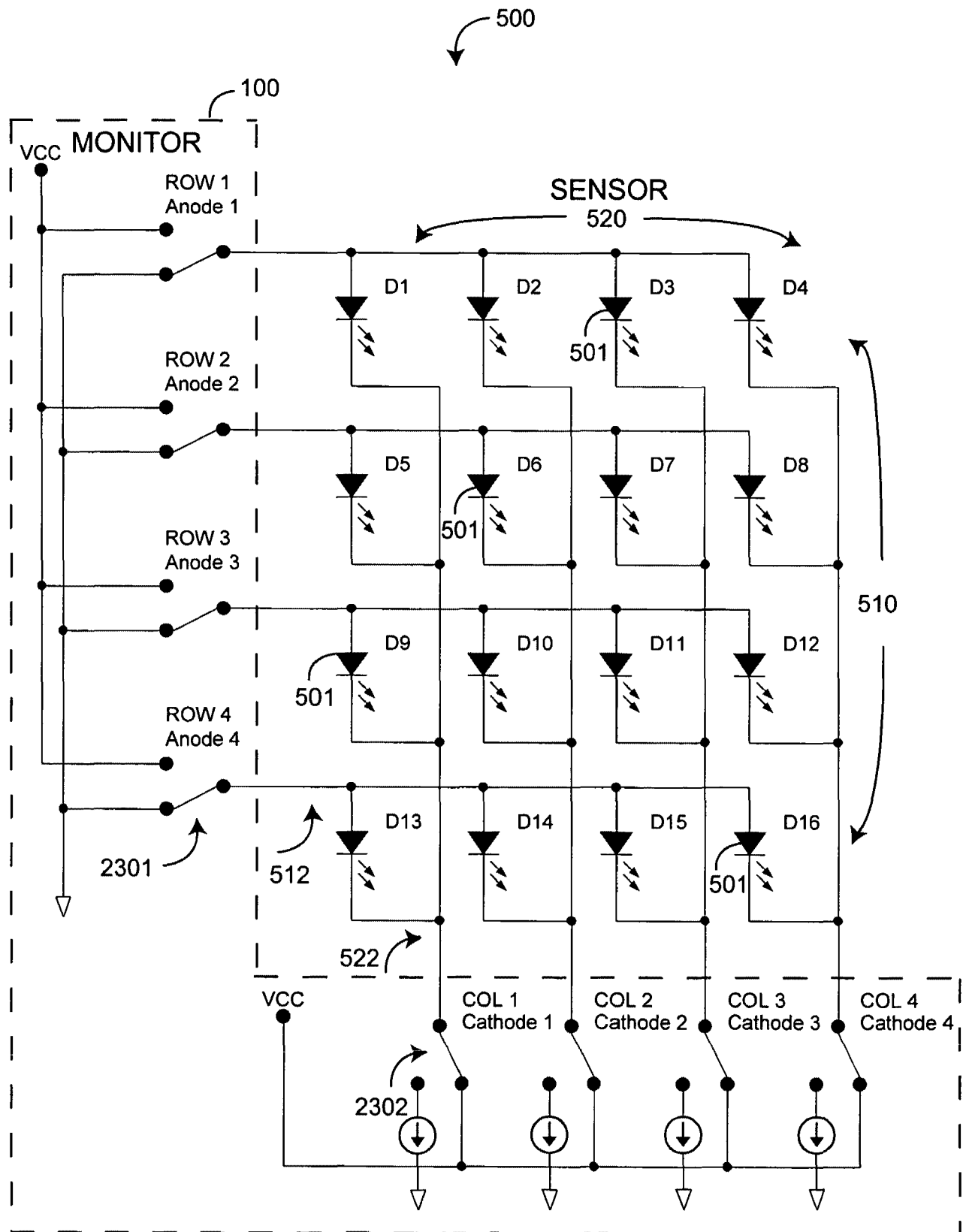


FIG. 5A

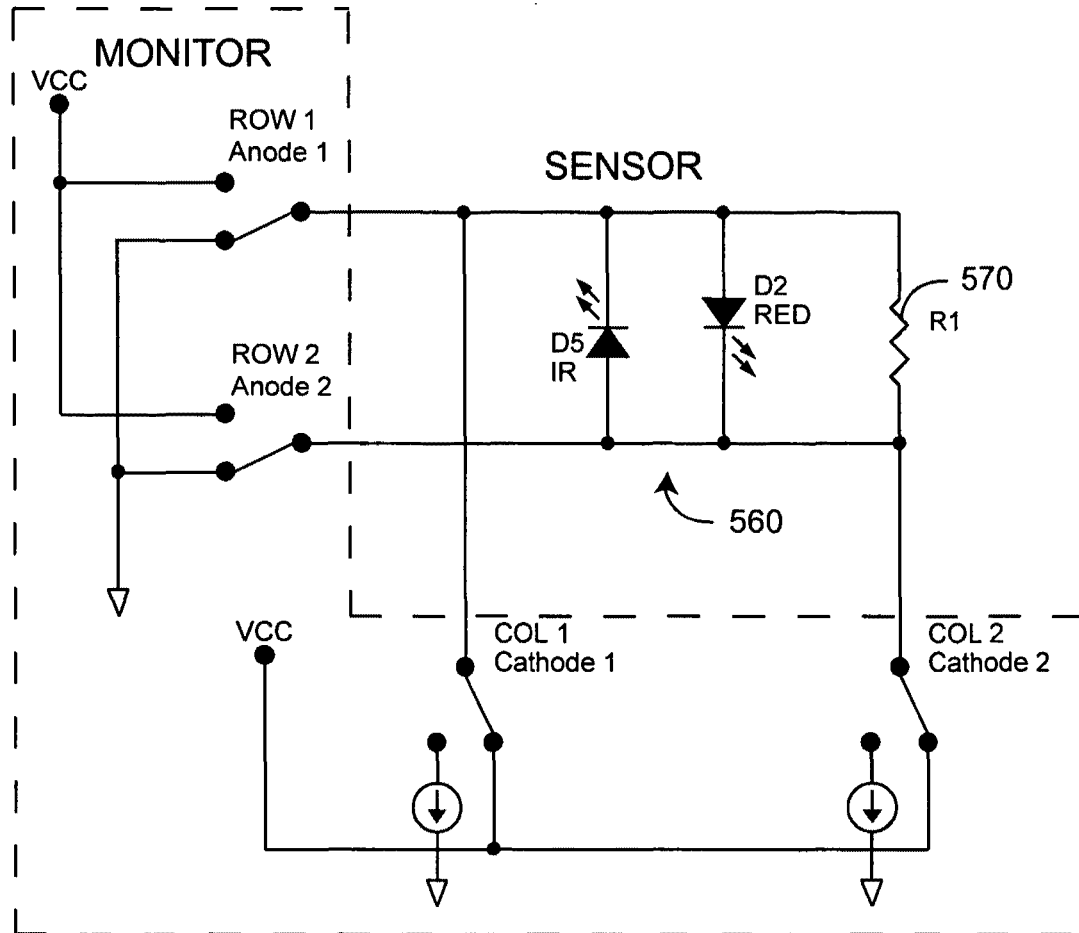


FIG. 5B

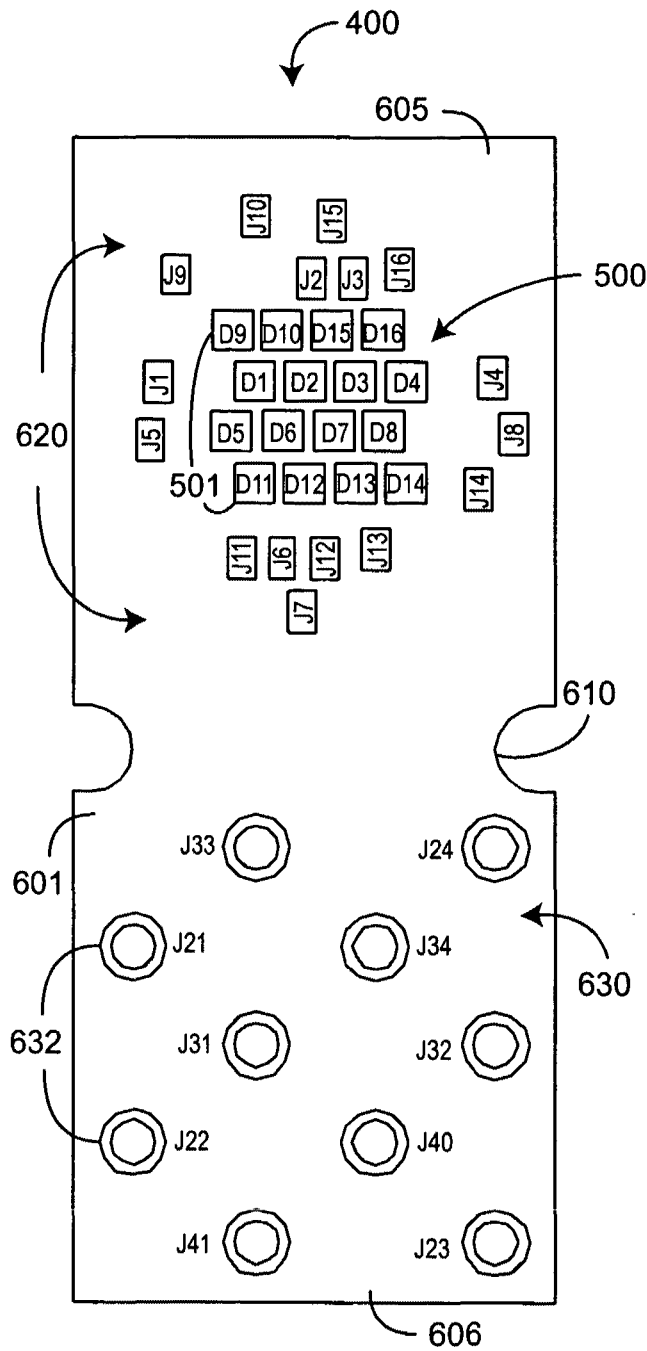


FIG. 6A

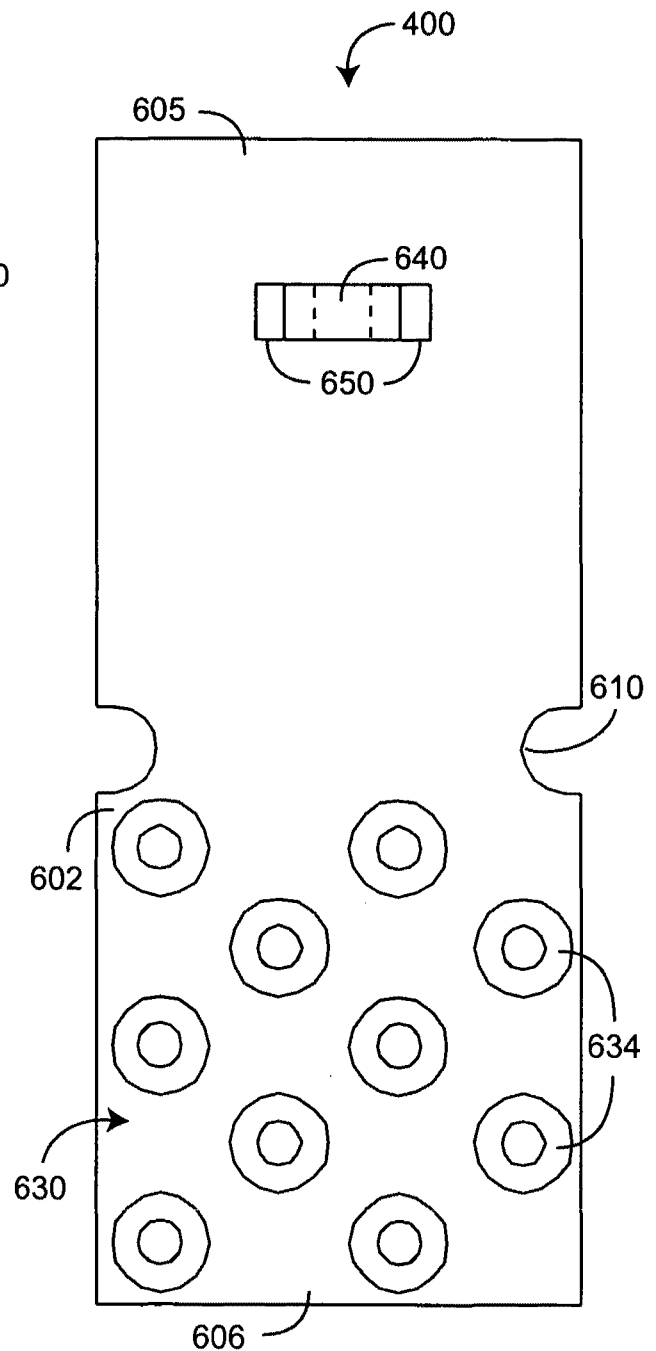


FIG. 6B

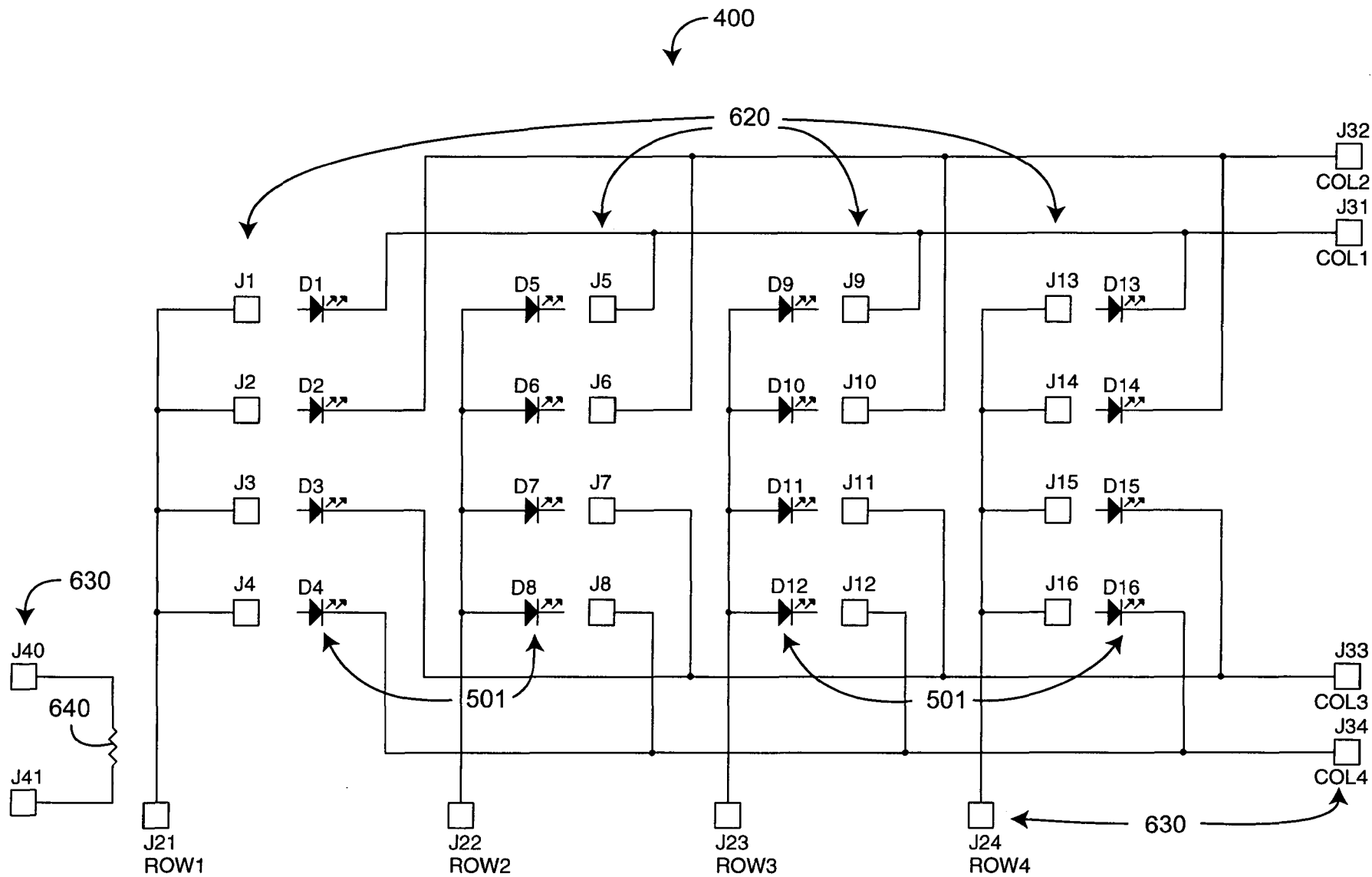


FIG. 7

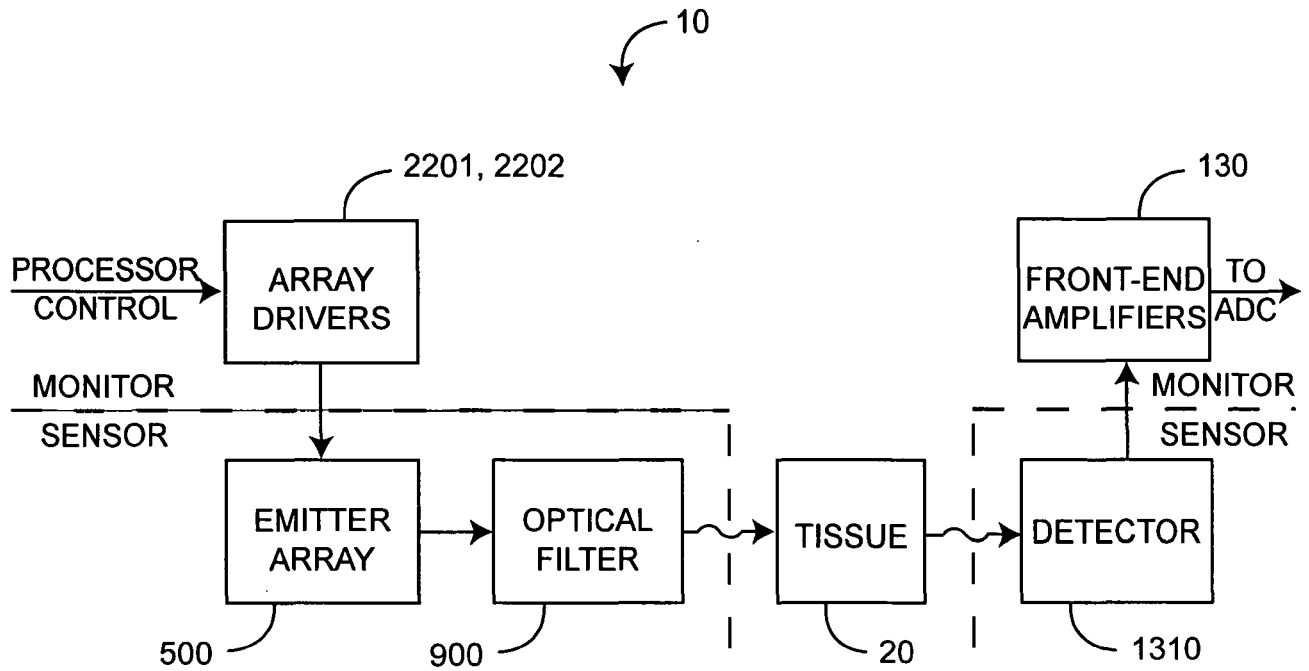


FIG. 8A

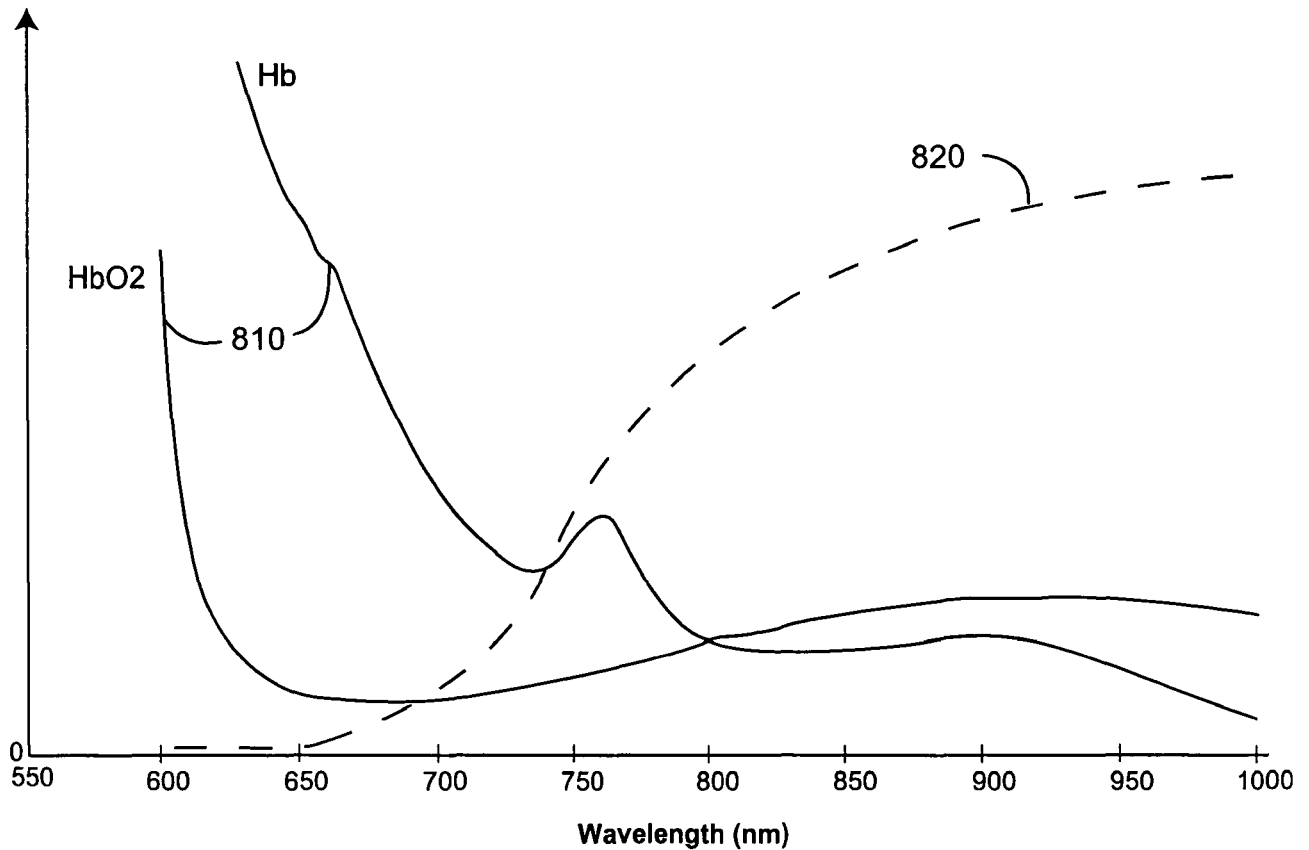


FIG. 8B

Title: Multiple Wavelength Sensor
 Applicant: Ammar B. Ali et al.
 Docket No.: MLR.001PR
 Attorney: Glenn Smith (949) 709-7164
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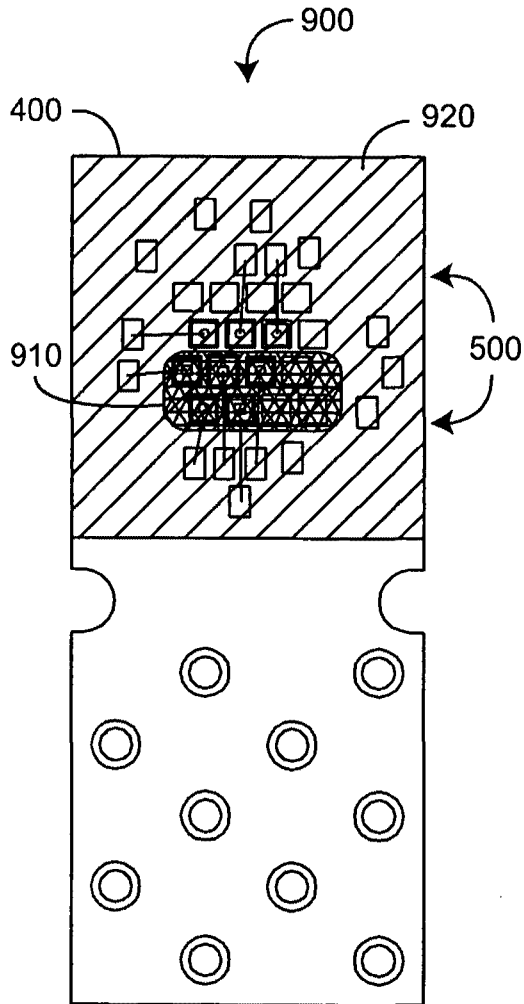


FIG. 9A

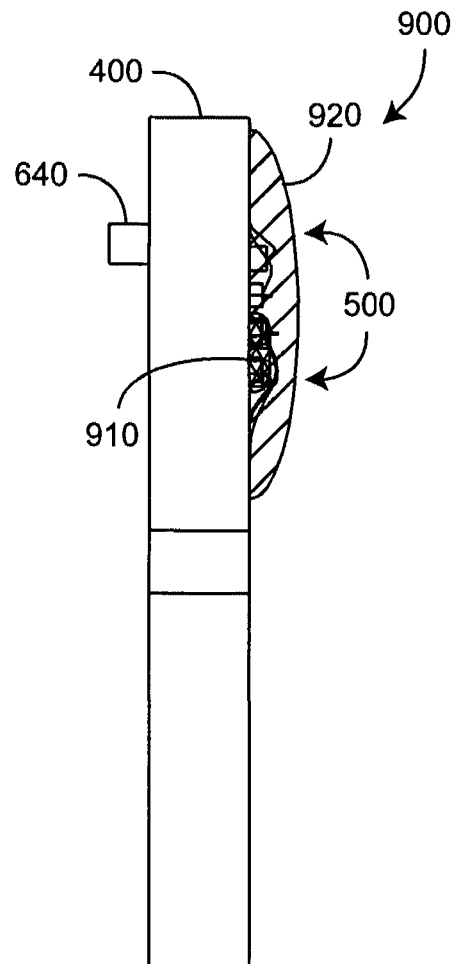
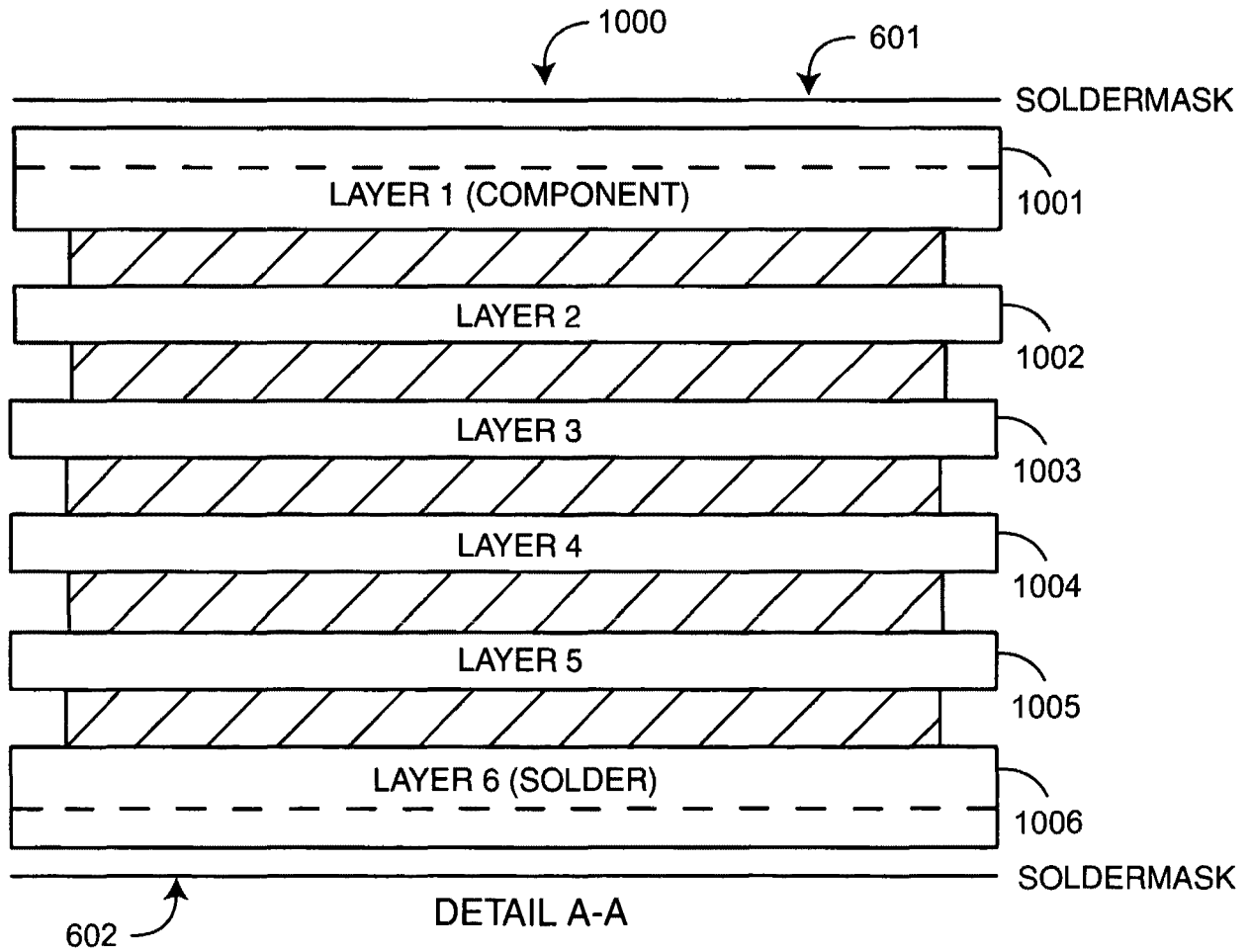
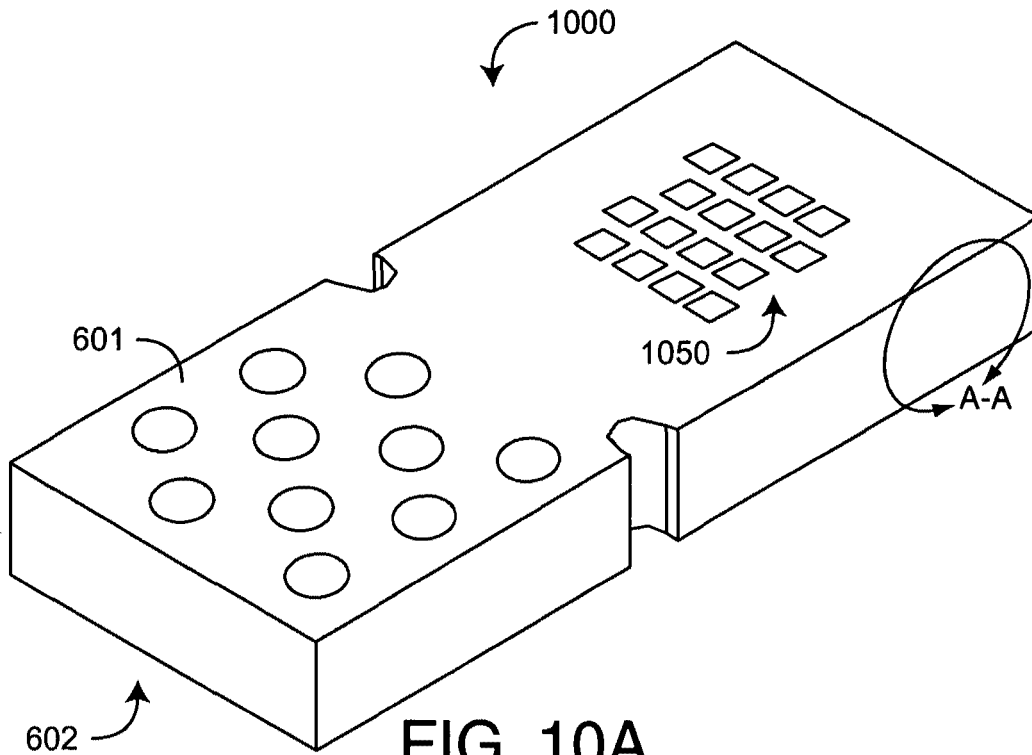


FIG. 9B



Title: Multiple Wavelength Sensor
Applicant: Ammar Al-Ali et al.
Docket No.: MLR.001PR
Attorney: Glenn Smith (949) 709-7164
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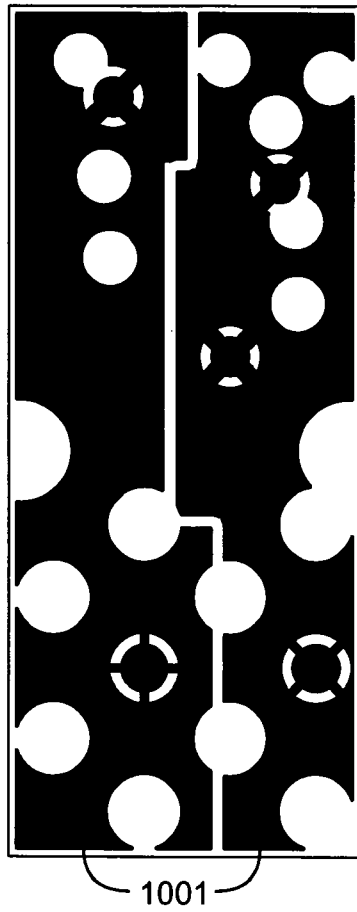



FIG. 10C

Title: Multiple Wavelength Sensor
Applicant: Ammar Al-Ali et al.
Docket No.: MLR.001PR
Attorney: Glenn Smith (949) 709-7164
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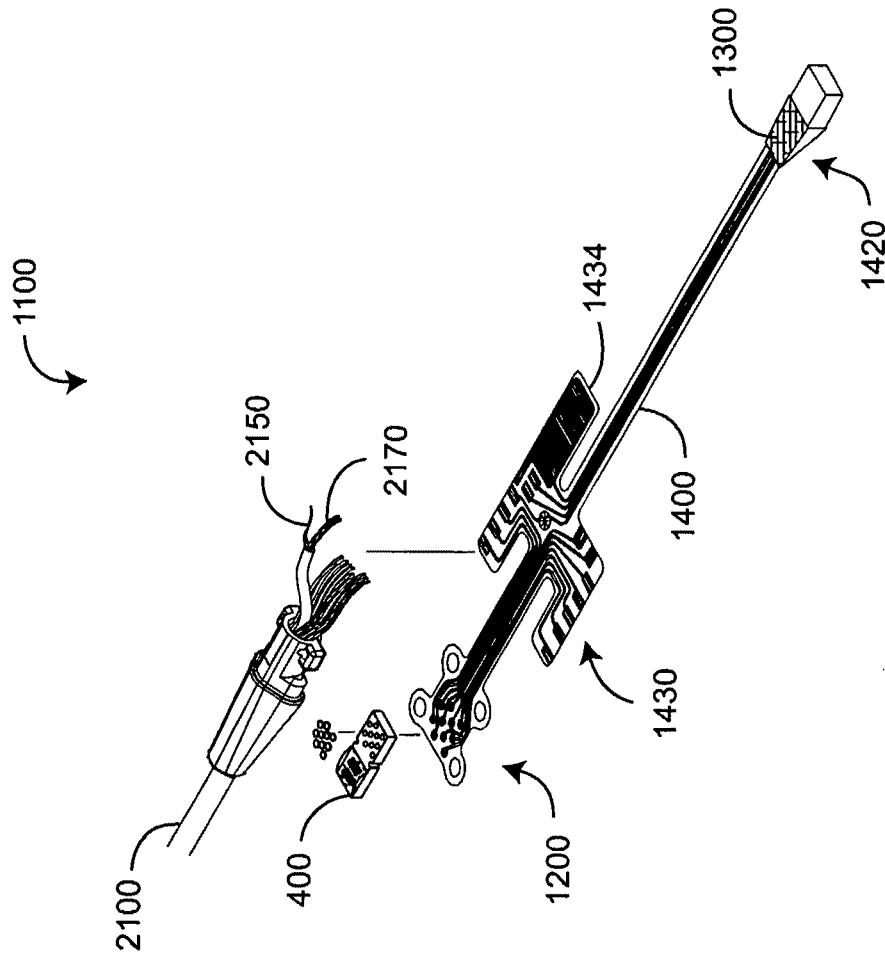


FIG. 11

Title: Multiple Wavelength Sensor
 Applicant: Ammar Al-Ali et al
 Docket No.: MLR.001PR
 Attorney: Glenn Smith (949) 709-7164
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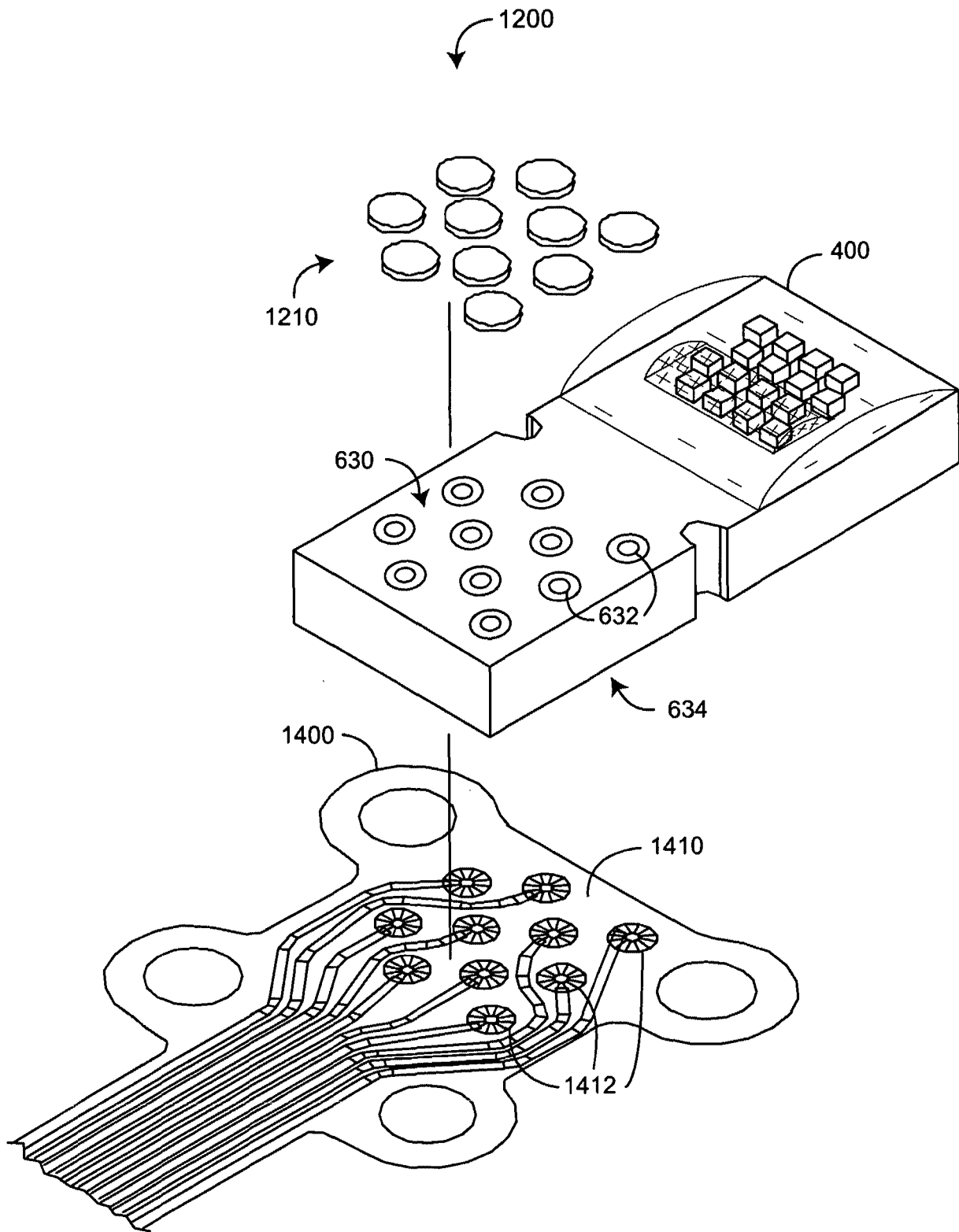


FIG. 12

Title: Multiple Wavelength Sensor
 Applicant: Ammar Al-Ali et al.
 Docket No.: MLR.001PR
 Attorney: Glenn Smith (949) 709-7164
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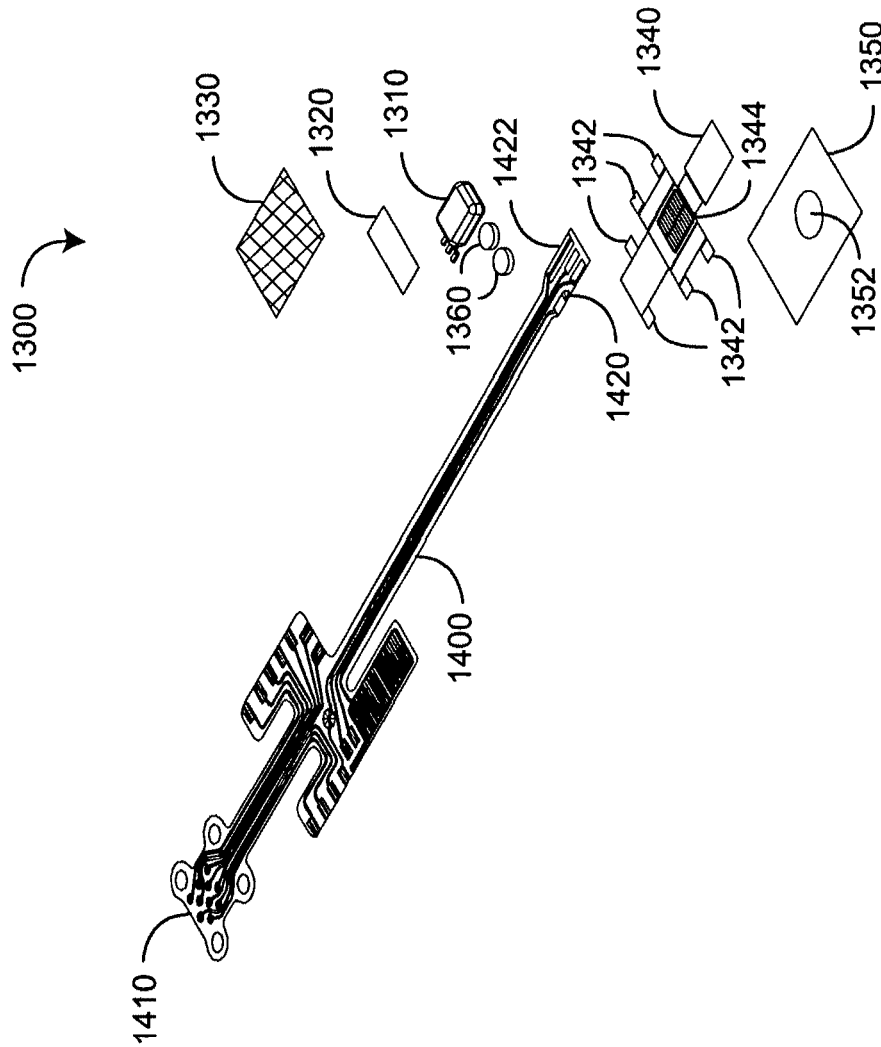


FIG. 13

Title: Multiple Wavelength Sensor
 Applicant: Ammar Ali et al
 Docket No.: MLR.001PR
 Attorney: Glenn Smith (949) 709-7164
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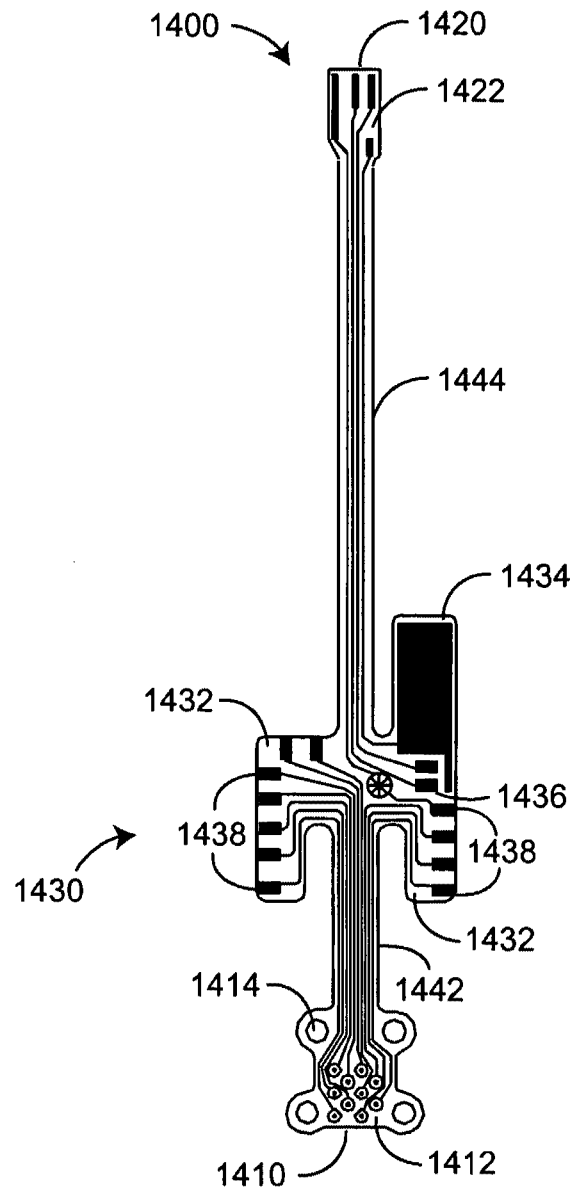


FIG. 14

Title: Multiple Wavelength Sensor
Applicant: Ammar Ali et al.
Docket No.: MLR.001PR
Attorney: Glenn Smith (949) 709-7164
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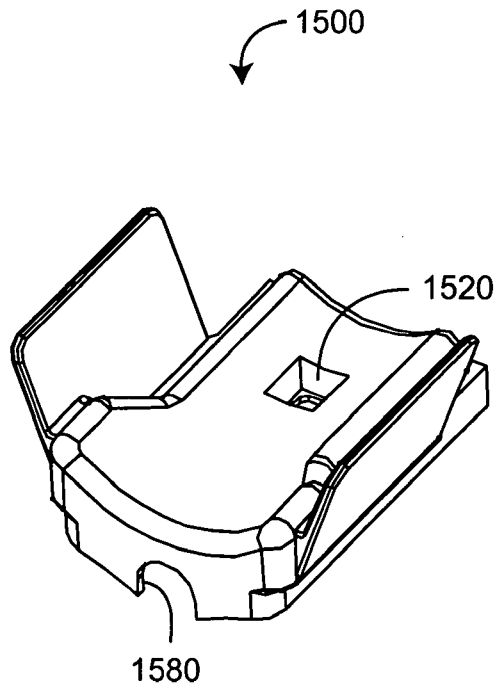


FIG. 15A

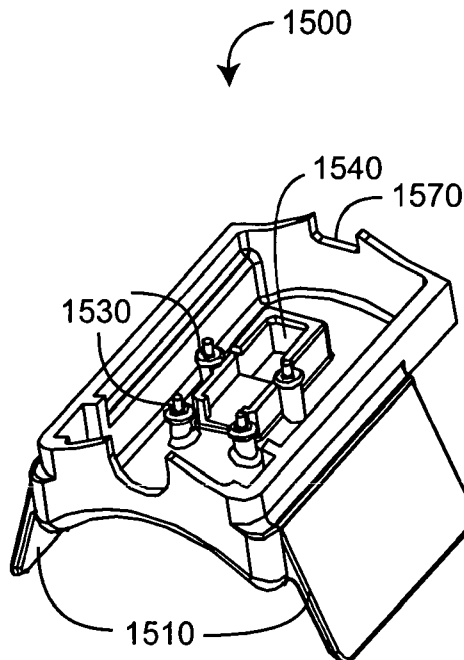


FIG. 15B

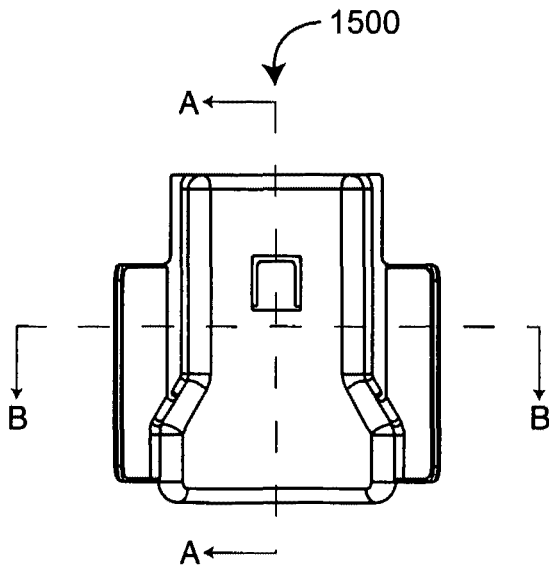
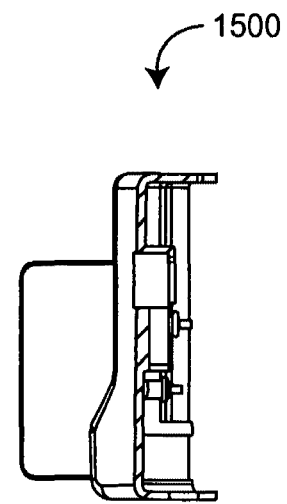


FIG. 15C



SECTION A-A

FIG. 15F

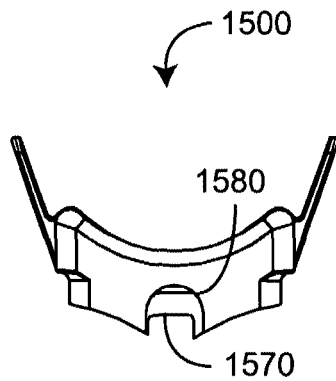


FIG. 15D

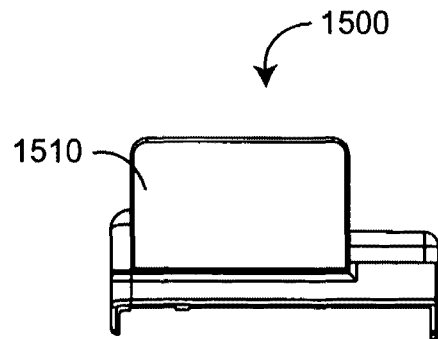


FIG. 15G

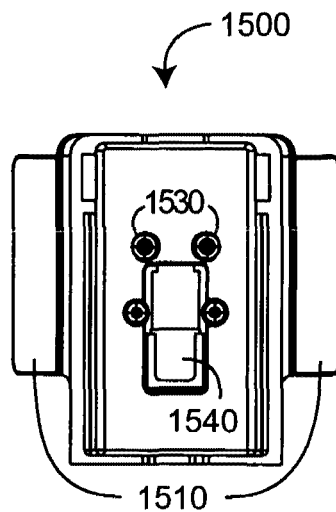
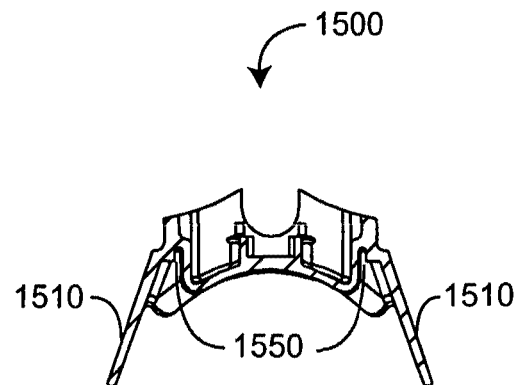


FIG. 15E



SECTION B-B

FIG. 15H

Title: Multiple Wavelength Sensor
Applicant: Ammar Al Ali et al.
Docket No.: MLR.001PR
Attorney: Glenn Smith (949) 709-7164
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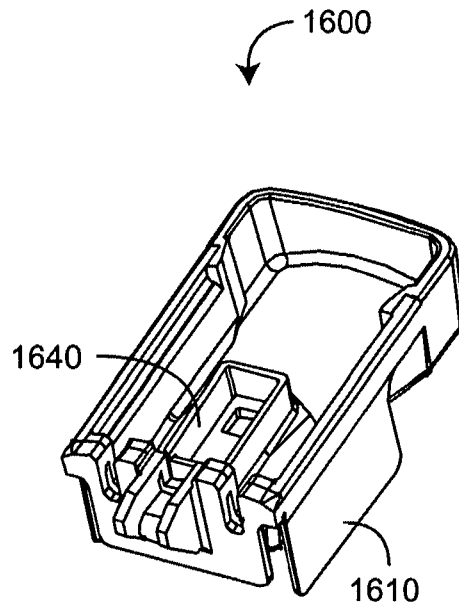


FIG. 16A

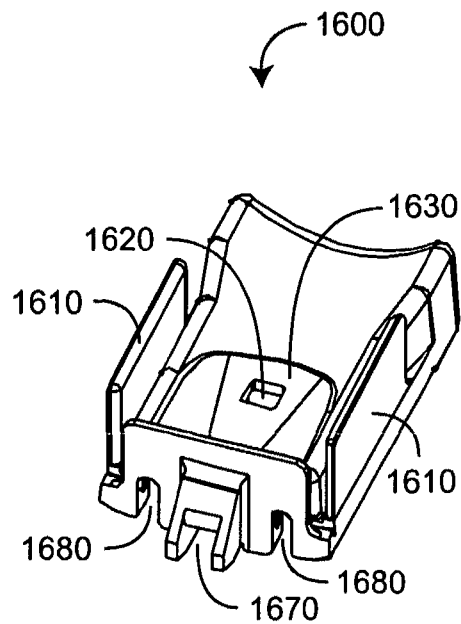


FIG. 16B

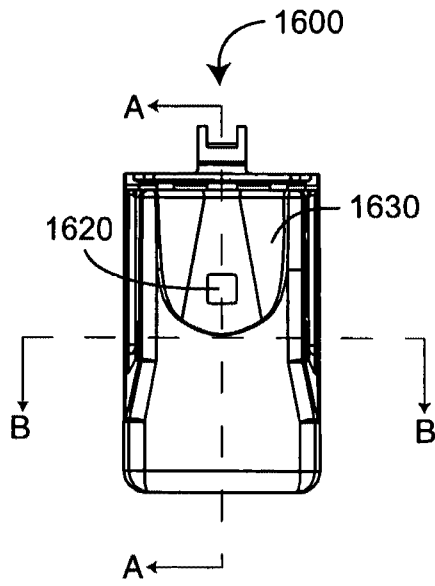


FIG. 16C

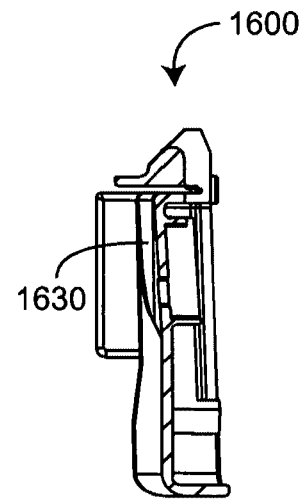


FIG. 16F

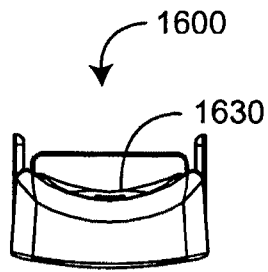


FIG. 16D

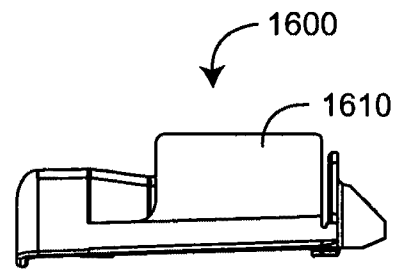


FIG. 16G

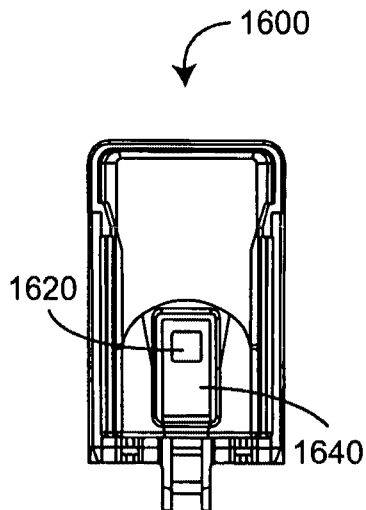


FIG. 16E

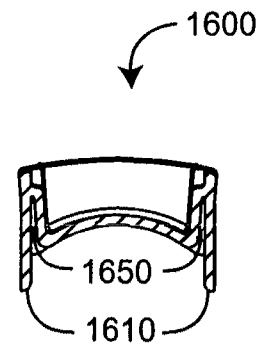


FIG. 16H

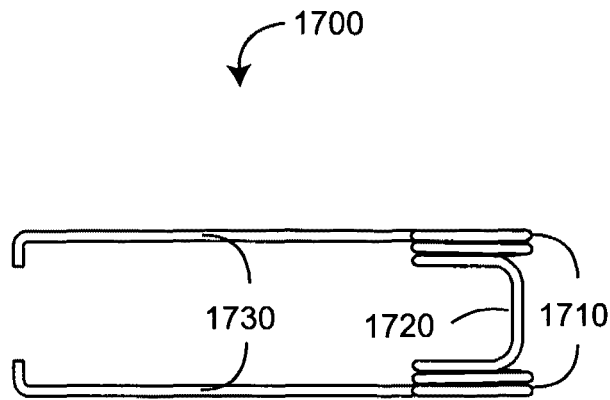


FIG. 17A

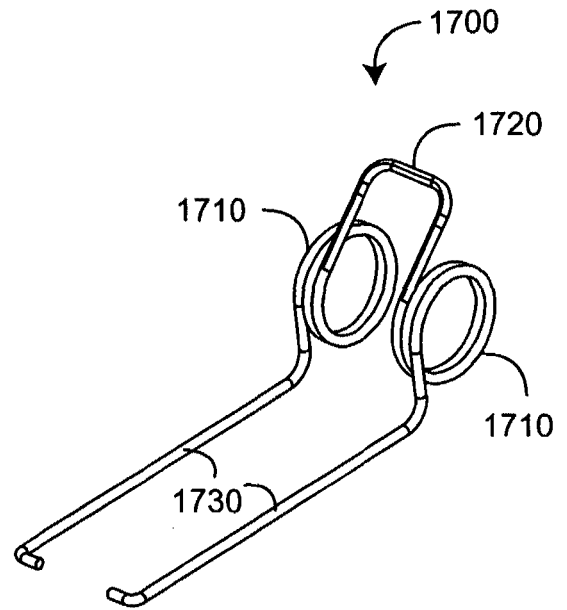


FIG. 17B

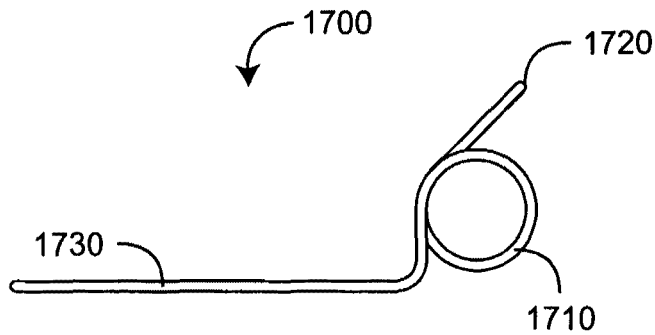


FIG. 17C

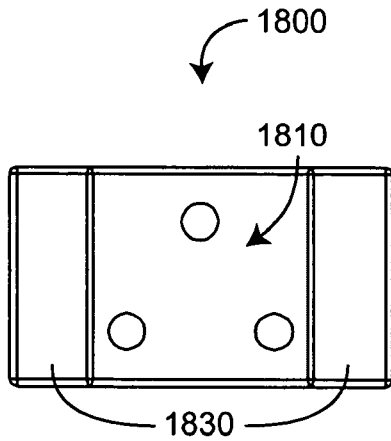


FIG. 18A

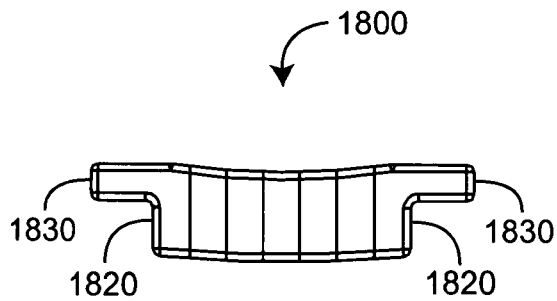


FIG. 18B

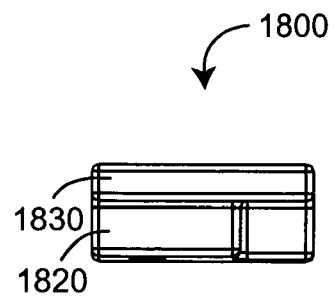


FIG. 18D

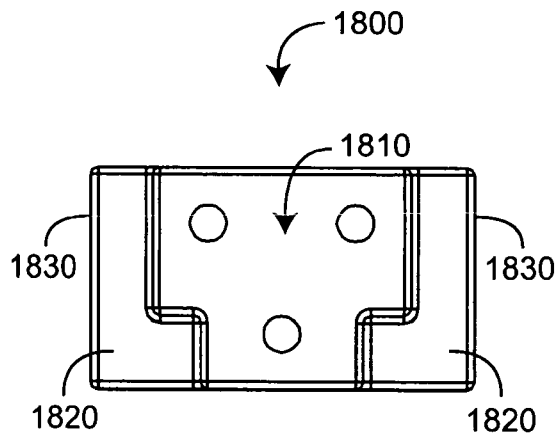


FIG. 18C

Title: Multiple Wavelength Sensor
 Applicant: Ammar Al Ali et al.
 Docket No.: MLR.001PR
 Attorney: Glenn Smith (949) 709-7164
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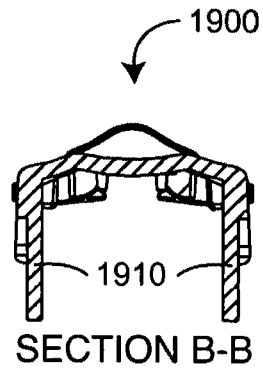


FIG. 19A

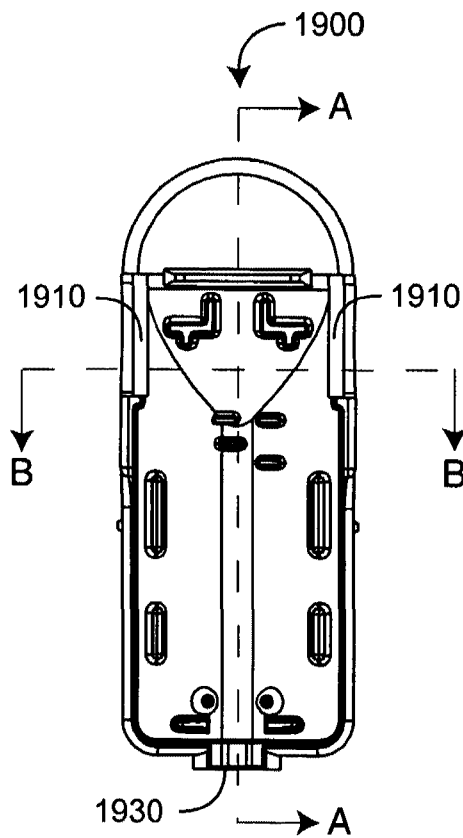
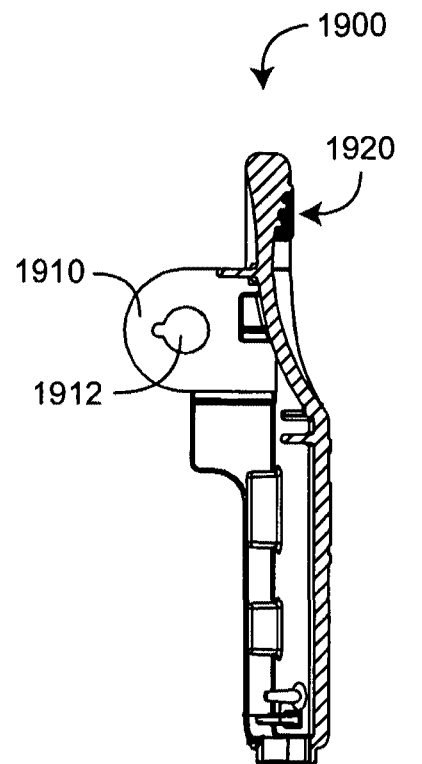


FIG. 19B



SECTION A-A
 FIG. 19D

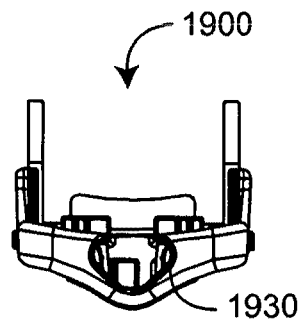


FIG. 19C

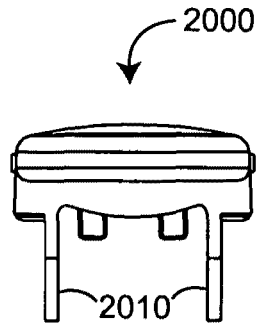


FIG. 20A

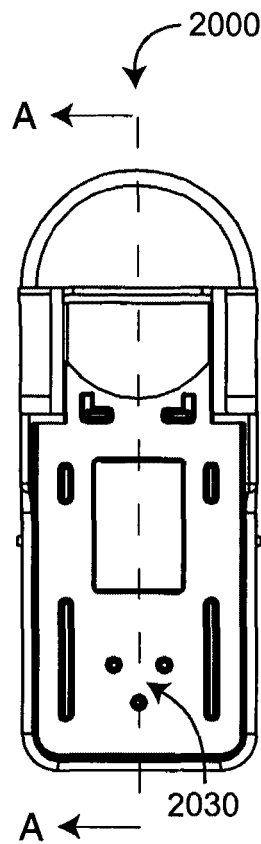
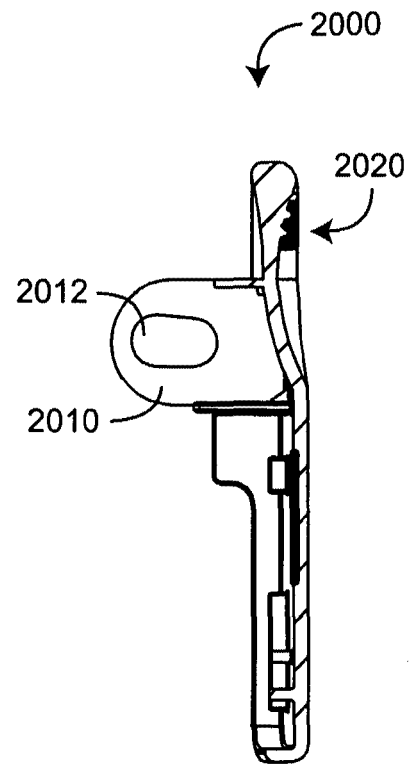


FIG. 20B



SECTION A-A
FIG. 20D

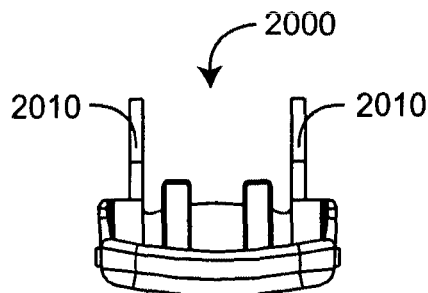


FIG. 20C

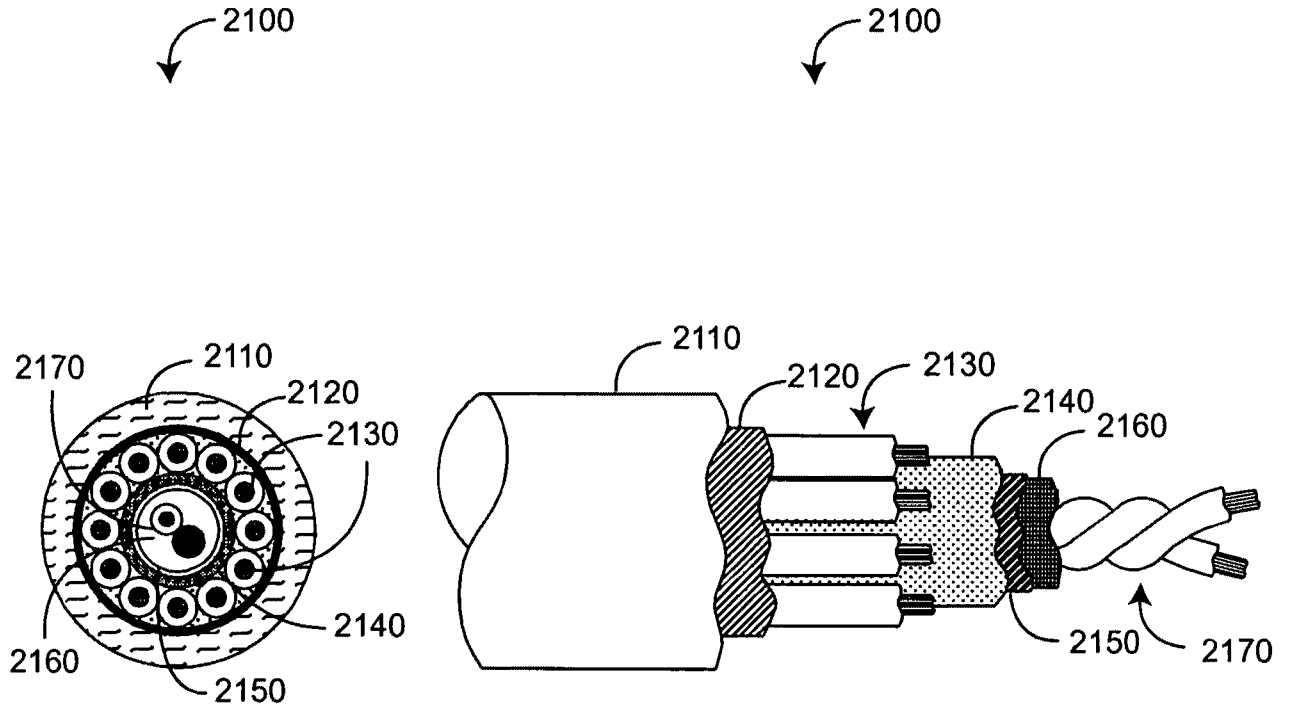
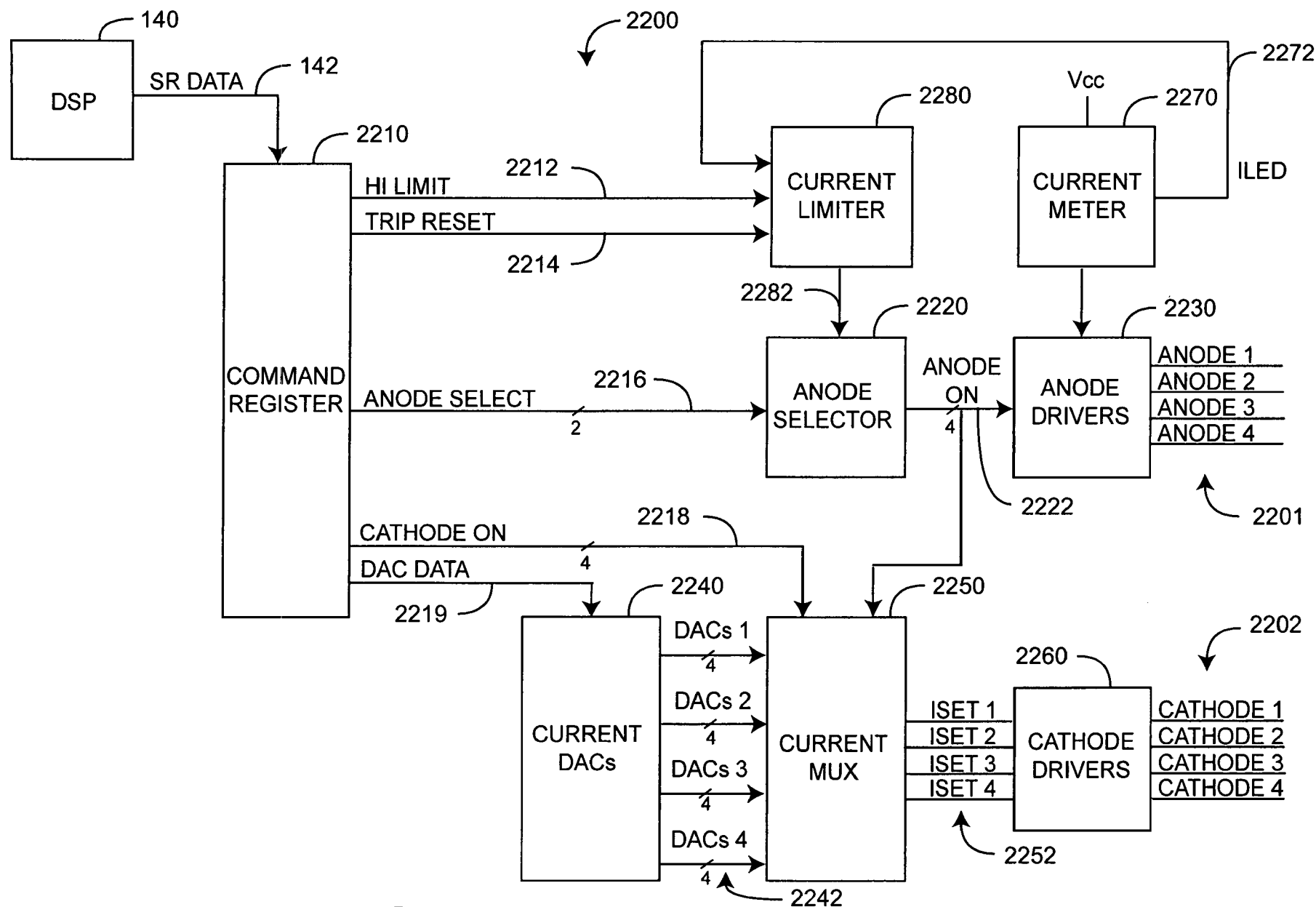


FIG. 21A

FIG. 21B



PATENT APPLICATION SERIAL NO. _____

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE
FEE RECORD SHEET

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EXHIBIT 19



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/028,655	09/22/2020	Robert A. Smith	MLR.002C6	3736
20995 7590 11/09/2020 KNOBBE MARTENS OLSON & BEAR LLP 2040 MAIN STREET FOURTEENTH FLOOR IRVINE, CA 92614			EXAMINER FARDANESH, MARJAN	
			ART UNIT	PAPER NUMBER
			3791	
			NOTIFICATION DATE	DELIVERY MODE
			11/09/2020	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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efiling@knobbe.com
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Office Action Summary**Application No.**

17/028,655

Applicant(s)

Smith et al.

Examiner

MARJAN FARDANESH

Art Unit

3791

AIA (FITF) Status

No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____. the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

- 5) ☐ Claim(s) _____ is/are pending in the application.
 5a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) _____ is/are allowed.
- 7) ☒ Claim(s) 21-49 is/are rejected.
- 8) ☐ Claim(s) _____ is/are objected to.
- 9) ☐ Claim(s) _____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☒ The drawing(s) filed on 09/22/2020 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

- a) ☐ All b) ☐ Some** c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)
 Paper No(s)/Mail Date 09/22/2020.
- 3) ☐ Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____.
- 4) ☐ Other: _____.

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DETAILED ACTION

Notice of Pre-AIA or AIA Status

1. The present application is being examined under the pre-AIA first to invent provisions.

Claim Rejections - 35 USC § 103

2. The following is a quotation of pre-AIA 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

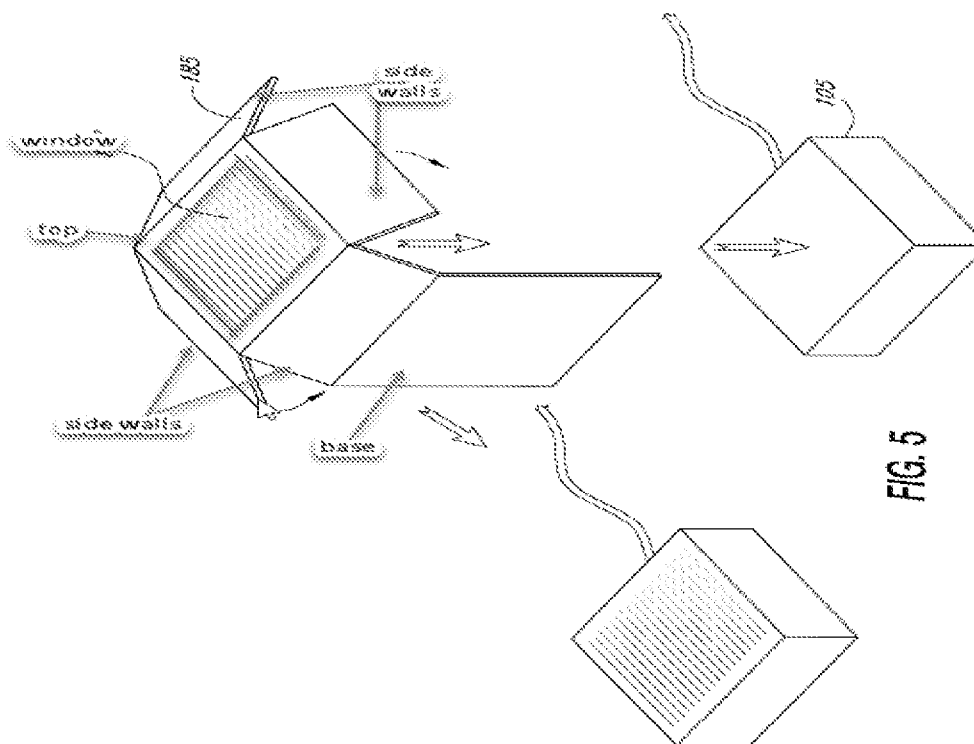
3. Claims 21-49 is/are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Schulz et al. (USPN 6,580,086) in view of USPN (5,355,880)

Regarding claims 21, 30, 39-41, Schulz et al. discloses a physiological monitoring device comprising: one or more LEDs recessed into a cavity, the one or more LEDs configured to emit light of at least three different wavelengths (Col.5 line 50-Col.6 line 60); at least one detector configured to detect at least a portion of the light emitted from the one or more after at least a portion of the light has been attenuated by tissue, the at least one detector configured to output at least one signal responsive to the detected light (Col.5 line 50-Col.6 line 60); a light block surrounding the at least one detector, the light block comprising a shoebox structure configured to recess the at least one detector into the shoebox structure, wherein the shoebox structure is formed of a black material, the shoebox structure further comprising a window on a top portion of the shoebox structure, the window comprising an area smaller than a detection surface

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area of the at least one detector (as shown in the figure below, Col.10 lines 30-50; as shown in the figure below the window is smaller than the entire detection surface area of the detector 105); and a processor configured to receive and process one or more signals responsive to the outputted at least one signal and determine a physiological parameter of a user responsive to the one or more signals (Col.12 line 20-Col.13 line 3). While Schulz et al. discloses one or more LEDs, Schulz fails to disclose at least three LEDs. Thomas et al. discloses reliable non-invasive measurement of blood gases including light emitting diodes and detector (figure 48, Col.28 line 50-Col.29 line 60). Therefore, it would have been obvious to one of ordinary skills in the art at the time the invention was made to incorporate the several light sources of Thomas et al. into the device of Schulz et al., since such modification provides several light sources in order to obtain multiple physiological parameters.



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Regarding claim 22, Schulz et al. in view of Thomas et al. discloses the at least three LEDs comprises at least eight LEDs (Thomas et al. figure 48, Col.28 line 50-Col.29 line 60).

Regarding claim 23, Schulz et al. in view of Thomas et al. discloses the at least eight LEDs comprises at least two LEDs of the same wavelength (Thomas et al. figure 48, Col.28 line 50-Col.29 line 60).

Regarding claim 24, Schulz et al. in view of Thomas et al. discloses the at least three LEDs comprises at least twelve LEDs (Thomas et al. Col.15 lines 2-6, Col.17 line 10-Col.18 line 15, Col.28 line 50-Col.29 line 60).

Regarding claim 25, Schulz et al. in view of Thomas et al. discloses at least two LEDs of the at least three LEDs are configured for concurrent activation (Thomas et al. Col.15 lines 2-6, Col.17 line 10-Col.18 line 15, Col.28 line 50-Col.29 line 60).

Regarding claim 26, Schulz et al. in view of Thomas et al. discloses the at least one detector comprises at least two detectors (Thomas et al. array detector, Col.15 lines 2-6, Col.17 line 10-Col.18 line 15, Col.28 line 50-Col.29 line 60).

Regarding claims 27, 47, Schulz et al. in view of Thomas et al. discloses the at least one detector comprises at least two detectors of different types (Thomas et al. array detector, Col.15 lines 2-6, Col.17 line 10-Col.18 line 15, Col.28 line 50-Col.29 line 60).

Regarding claim 28, Schulz et al. in view of Thomas et al. discloses the window provides an optical path from the tissue to the at least one detector (as shown in the figure above and figures 2-3 of Schulz et al.).

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Regarding claim 29, Schulz et al. in view of Thomas et al. discloses the window provides an optical path from the at least three LEDs to the tissue (as shown in the figure above and figures 2-3 of Schulz et al.).

Regarding claim 31, Schulz et al. in view of Thomas et al. discloses the at least three LEDs comprises at least eight LEDs (figure 48, Col.28 line 50-Col.29 line 60).

Regarding claim 32, Schulz et al. in view of Thomas et al. discloses the at least eight LEDs comprises at least two LEDs of the same wavelength (figure 48, Col.28 line 50-Col.29 line 60).

Regarding claim 33, 45, Schulz et al. in view of Thomas et al. discloses the at least three LEDs comprises at least twelve LEDs (Thomas et al. Col.15 lines 2-6, Col.17 line 10-Col.18 line 15, Col.28 line 50-Col.29 line 60).

Regarding claims 34, 42, Schulz et al. in view of Thomas et al. discloses at least two LEDs of the at least three LEDs are configured for concurrent activation (Thomas et al. Col.15 lines 2-6, Col.17 line 10-Col.18 line 15, Col.28 line 50-Col.29 line 60).

Regarding claims 35, 46, Schulz et al. in view of Thomas et al. discloses the at least one detector comprises at least two detectors (Thomas et al. array detector, Col.15 lines 2-6, Col.17 line 10-Col.18 line 15, Col.28 line 50-Col.29 line 60).

Regarding claim 36, Schulz et al. in view of Thomas et al. discloses the at least one detector comprises at least two detectors of different types (Thomas et al. array detector, Col.15 lines 2-6, Col.17 line 10-Col.18 line 15, Col.28 line 50-Col.29 line 60).

Regarding claim 37, Schulz et al. in view of Thomas et al. discloses the window provides an optical path from the tissue to the at least one detector(as shown in the figure above and figures 2-3 of Schulz et al.).

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Regarding claim 38, Schulz et al. in view of Thomas et al. discloses the window provides an optical path from the at least three LEDs to the tissue (as shown in the figure above and figures 2-3 of Schulz et al.).

Regarding claim 43, Schulz et al. in view of Thomas et al. discloses the at least three LEDs comprises at least eight LEDs (figure 48, Col.28 line 50-Col.29 line 60).

Regarding claim 44, Schulz et al. in view of Thomas et al. discloses the at least eight LEDs comprises at least two LEDs of the same wavelength (figure 48, Col.28 line 50-Col.29 line 60).

Regarding claim 48, Schulz et al. in view of Thomas et al. discloses the at least a portion of the light passes through the window after it interacts with the body tissue (as shown in the figure above and figures 2-3 of Schulz et al.).

Regarding claim 49, Schulz et al. in view of Thomas et al. discloses the at least a portion of the light passes through the window before it interacts with the body tissue (as shown in the figure above and figures 2-3 of Schulz et al.).

Conclusion

4. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Fuse et al. (5,313,940) discloses a finger clip sensor including emitters and detectors and shoe-like light block wherein the detector(s) is located inside the shoe-like light block (figures 3-7, Col.3 line 5-Col.4 line 20).

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARJAN FARDANESH whose telephone number is (571)270-5508. The examiner can normally be reached on Monday-Friday 9:00-17:00.

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Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at <http://www.uspto.gov/interviewpractice>.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jacqueline Cheng can be reached on (571)272-5596. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <https://ppair-my.uspto.gov/pair/PrivatePair>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MARJAN FARDANESH/
Examiner, Art Unit 3791

MLR.002C6

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Inventor : Robert A. Smith
App. No. : 17/028655
Filed : September 22, 2020
For : MULTIPLE WAVELENGTH SENSOR EMITTERS
Examiner : Fardanesh, Marian
Art Unit : 3791
Conf. No. : 3736

RESPONSE TO OFFICE ACTION DATED NOVEMBER 9, 2020

Mail Stop Amendment

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Commissioner:

In response to the Non-Final Office Action dated November 9, 2020, please consider the following:

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Summary of Interview begins on page 6 of this paper.

Remarks/Arguments begin on page 7 of this paper.

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Filing Date: September 22, 2020

AMENDMENTS TO THE CLAIMS

1-20. (Canceled)

21. (**Currently Amended**) A physiological monitoring device comprising:

at least three LEDs recessed into a cavity, the at least three LEDs configured to emit light of at least three different wavelengths;

at least one detector configured to detect at least a portion of the light emitted from the at least three LEDs after at least a portion of the light has been attenuated by tissue, the at least one detector configured to output at least one signal responsive to the detected light;

a light block surrounding the at least one detector, the light block comprising a shoebox structure configured to recess the at least one detector into the shoebox structure, wherein the shoebox structure is at least partially formed of a black material, wherein a top of the shoebox structure includes only one opening through which light is configured to pass~~further comprising a window on a top portion of the shoebox structure, the opening window~~ comprising an area smaller than a detection surface area of the at least one detector; and

a processor configured to receive and process one or more signals responsive to the outputted at least one signal and determine a physiological parameter of a user responsive to the one or more signals.

22. (Previously Presented) The device of Claim 21, wherein the at least three LEDs comprises at least eight LEDs.

23. (Previously Presented) The device of Claim 22, wherein the at least eight LEDs comprises at least two LEDs of the same wavelength.

24. (Previously Presented) The device of Claim 21, wherein the at least three LEDs comprises at least twelve LEDs.

25. (Previously Presented) The device of Claim 21, wherein at least two LEDs of the at least three LEDs are configured for concurrent activation.

26. (Previously Presented) The device of Claim 21, wherein the at least one detector comprises at least two detectors.

27. (Previously Presented) The device of Claim 21, wherein the at least one detector comprises at least two detectors of different types.

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28. **(Currently Amended)** The device of Claim 21, wherein the ~~window~~opening provides an optical path from the tissue to the at least one detector.

29. **(Currently Amended)** The device of Claim 21, wherein the opening ~~window~~ provides an optical path from the at least three LEDs to the tissue.

30. **(Currently Amended)** A physiological monitoring device comprising:

at least three LEDs recessed into a cavity, the at least three LEDs configured to emit light of at least three different wavelengths;

at least one detector configured to detect at least a portion of the light emitted from the at least three LEDs after at least a portion of the light has been attenuated by tissue, the at least one detector configured to output at least one signal responsive to the detected light;

an electromagnetic interference shield positioned between the at least three LEDs and the at least one detector;

a light block surrounding the at least one detector, the light block at least partially formed of black materials, the light block comprising a base, four side walls and a top forming an enclosure, wherein the light block comprises a window, the window having an area smaller than a detection surface area of the at least one detector; and

a processor configured to receive and process one or more signals responsive to the outputted at least one signal and determine a physiological parameter of a user responsive to the one or more signals.

31. **(Previously Presented)** The device of Claim 30, wherein the at least three LEDs comprises at least eight LEDs.

32. **(Previously Presented)** The device of Claim 31, wherein the at least eight LEDs comprises at least two LEDs of the same wavelength.

33. **(Previously Presented)** The device of Claim 30, wherein the at least three LEDs comprises at least twelve LEDs.

34. **(Previously Presented)** The device of Claim 30, wherein at least two LEDs of the at least three LEDs are configured for concurrent activation.

35. **(Previously Presented)** The device of Claim 30, wherein the at least one detector comprises at least two detectors.

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36. (Previously Presented) The device of Claim 30, wherein the at least one detector comprises at least two detectors of different types.

37. (Previously Presented) The device of Claim 30, wherein the window provides an optical path from the tissue to the at least one detector.

38. (Previously Presented) The method of Claim 38, wherein the window provides an optical path from the at least three LEDs to the tissue.

39. **(Currently Amended)** A method for determining a physiological parameter of a living patient, the method comprising:

positioning a sensor with respect to body tissue of a living patient, the sensor comprising at least three LEDs, at least one detector, and a light block at least partially surrounding the at least one detector, wherein a top of the light block comprises only one opening through which light is configured to pass~~comprising a window~~;

activating the at least three LEDs such that at least three wavelengths of light are emitted from the at least three LEDs;

detecting, at the at least one detector, at least a portion of the light emitted from the at least three LEDs after at least a portion of the light has been attenuated by the body tissue and passed through the ~~opening~~top of the light block of the ~~top of the light block~~, wherein the at least one detector outputs at least one signal responsive to the detected light; and

determining a physiological parameter of the living patient responsive to the outputted at least one signal.

40. **(Currently Amended)** The method of Claim 39, wherein an area of the ~~window~~ opening is smaller than a detection surface area of the at least one detector.

41. (Previously Presented) The method of Claim 39, wherein the light block is formed of black materials and further comprises a base, side walls, and a top forming an enclosure, and wherein the at least one detector is positioned in the enclosure.

42. (Previously Presented) The method of Claim 39, wherein said activating the at least three LEDs comprises concurrently activating at least two LEDs of the at least three LEDs.

43. (Previously Presented) The method of Claim 39, wherein the at least three LEDs comprises at least eight LEDs.

44. (Previously Presented) The method of Claim 43, wherein the at least eight LEDs comprises at least two LEDs of the same wavelength.

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45. (Previously Presented) The method of Claim 39, wherein the at least three LEDs comprises at least twelve LEDs.

46. (Previously Presented) The method of Claim 39, wherein the at least one detector comprises at least two detectors.

47. (Previously Presented) The method of Claim 39, wherein the at least one detector comprises at least two detectors of different types.

48. **Currently Amended**) The method of Claim 39, wherein the at least a portion of the light passes through the ~~window~~opening after it interacts with the body tissue.

49. **(Currently Amended)** The method of Claim 39, wherein the at least a portion of the light passes through the opening~~window~~ before it interacts with the body tissue.

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SUMMARY OF INTERVIEW

Attendees, Date and Type of Interview

A telephonic interview (the “Interview”) was conducted on February 5, 2021 and attended by Examiner Fardanesh, and Applicant’s representative David Grant (reg. no. 74,373).

Identification of Claims Discussed

All claims

Identification of Prior Art Discussed

- U.S. Patent No. 6,580,086 to Schulz
- U.S. Patent No. 5,355,880 to Thomas

Proposed Amendments, Principal Arguments, and Other Matters

Examiners and Applicant’s representatives discussed the technology disclosed in the specification as well as the outstanding rejections under § 103.

Results of Interview

Without acquiescence and solely to advance prosecution of the present application, Applicant’s representative proposed amendments substantially similar to those presented herein. Examiner Fardanesh agreed that the claims overcome the outstanding rejections under § 103. No agreement was reached with respect to allowability or with respect to the outstanding rejections under § 112.

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REMARKS

This paper is filed in response to the Office Action March 20, 2020 (hereinafter “Office Action”) in connection with the above-referenced application. In response to the Office Action, Applicant has amended Claims 21, 28-30, 39, 40, 48, and 49. No claims were canceled or added. Accordingly, Claims 21-49 are pending and are presented for further examination. No new subject matter is believed to have been added to the present application by way of the amendments. Example support for the amendments can be found at least in paragraphs [0087] and [0092] and Figures 24 and 46. For the following reasons, Applicant respectfully requests reconsideration of the claims of the present application.

Rejections under 35 U.S.C. § 103

Claims 21-49 were rejected under 35 U.S.C. § 103 as allegedly being unpatentable over U.S. Patent No. 6,580,086 to Schulz et al. (hereinafter “Schulz”) in view of U.S. Patent No. 5,355,880 to Thomas et al. (hereinafter “Thomas”). Applicant respectfully traverses each of these rejections, the characterizations of the pending claims, and each and every implicit and/or explicit potential reliance on Official Notice. In view of the foregoing amendments and for at least the reasons set forth below, Applicant respectfully disagrees and requests reconsideration of the aforementioned claims.

Claims 21-29

Claim 21 has been amended as recited above and substantially as discussed during the Interview. For example, Claim 21 has been amended to recite, in part:

at least three LEDs recessed into a cavity, the at least three LEDs configured to emit light of at least three different wavelengths;

at least one detector configured to detect at least a portion of the light emitted from the at least three LEDs after at least a portion of the light has been attenuated by tissue, the at least one detector configured to output at least one signal responsive to the detected light;

a light block surrounding the at least one detector, the light block comprising a shoebox structure configured to recess the at least one detector into the shoebox structure, wherein the shoebox structure is at least partially formed of a black material, wherein a top of the shoebox structure includes only one opening through which light is configured to pass, the opening comprising an area

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smaller than a detection surface area of the at least one detector;
and

a processor configured to receive and process one or more signals responsive to the outputted at least one signal and determine a physiological parameter of a user responsive to the one or more signals.

As discussed during the interview and agreed to by the Examiner, Shultz, Thomas, and the other references of record do not teach or make obvious each and every recitation of Claim 21. Accordingly, Applicant requests withdrawal of the rejection of Claim 21 under 35 U.S.C. § 103.

Applicant additionally requests the rejections under 35 U.S.C. § 103 of Claims 21-27, each of which depends either directly or indirectly from Claim 21, be withdrawn at least for reasons similar to those discussed above with respect to Claim 21, and for the unique patentable features recited by each.

Claims 30-38

Claim 30 has been amended as recited above and substantially as discussed during the Interview. For example, Claim 30 has been amended to recite, in part:

at least three LEDs recessed into a cavity, the at least three LEDs configured to emit light of at least three different wavelengths;

at least one detector configured to detect at least a portion of the light emitted from the at least three LEDs after at least a portion of the light has been attenuated by tissue, the at least one detector configured to output at least one signal responsive to the detected light;

an electromagnetic interference shield positioned between the at least three LEDs and the at least one detector;

a light block surrounding the at least one detector, the light block at least partially formed of black materials, the light block comprising a base, four side walls and a top forming an enclosure, wherein the light block comprises a window, the window having an area smaller than a detection surface area of the at least one detector; and

a processor configured to receive and process one or more signals responsive to the outputted at least one signal and determine a physiological parameter of a user responsive to the one or more signals.

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As discussed during the interview and agreed to by the Examiner, Shultz, Thomas, and the other references of record do not teach or make obvious each and every recitation of Claim 30. Accordingly, Applicant requests withdrawal of the rejection of Claim 30 under 35 U.S.C. § 103.

Applicant additionally requests the rejections under 35 U.S.C. § 103 of Claims 31-38, each of which depends either directly or indirectly from Claim 30, be withdrawn at least for reasons similar to those discussed above with respect to Claim 30, and for the unique patentable features recited by each.

Claims 39-49

Claim 39 has been amended as recited above and substantially as discussed during the Interview. For example, Claim 39 has been amended to recite, in part:

positioning a sensor with respect to body tissue of a living patient, the sensor comprising at least three LEDs, at least one detector, and a light block at least partially surrounding the at least one detector, wherein a top of the light block comprises only one opening through which light is configured to pass;

activating the at least three LEDs such that at least three wavelengths of light are emitted from the at least three LEDs;

detecting, at the at least one detector, at least a portion of the light emitted from the at least three LEDs after at least a portion of the light has been attenuated by the body tissue and passed through the opening of the top of the light block, wherein the at least one detector outputs at least one signal responsive to the detected light; and

determining a physiological parameter of the living patient responsive to the outputted at least one signal.

As discussed during the interview and agreed to by the Examiner, Shultz, Thomas, and the other references of record do not teach or make obvious each and every recitation of Claim 39. Accordingly, Applicant requests withdrawal of the rejection of Claim 39 under 35 U.S.C. § 103.

Applicant additionally requests the rejections under 35 U.S.C. § 103 of Claims 30-49, each of which depends either directly or indirectly from Claim 39, be withdrawn at least for reasons similar to those discussed above with respect to Claim 39, and for the unique patentable features recited by each.

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No Disclaimer or Disavowals

Applicant respectfully submits that the claims are in condition for allowance. Furthermore, any remarks in support of patentability of one claim should not be imputed to any other claim, even if similar terminology is used. Any remarks referring to only a portion of a claim should not be understood to base patentability on that portion or that the element discussed is essential or critical; rather, patentability must rest on each claim taken as a whole. Applicant respectfully traverses each of the Examiner's rejections and each of the Examiner's assertions regarding what the prior art shows or teaches, even if not expressly discussed herein. Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, no acquiescence, disclaimer or estoppel is intended or should be implied thereby. Applicant is not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made only to expedite prosecution of the present application and are without prejudice to the presentation or assertion, in the future, of claims relating to the same or similar subject matter. Applicant may not have presented in all cases, arguments concerning whether the applied references render the claims anticipated or obvious, and Applicant reserves the right to later submit additional arguments of patentability. Applicant also reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure. Accordingly, reviewers of this or any parent, child, or related prosecution history shall not reasonably infer that Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: February 9, 2021

By: /David J. Grant/
David Grant
Registration No. 74,373
Registered Practitioner
202) 640-6400

34072596



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/028,655	09/22/2020	Robert A. Smith	MLR.002C6	3736

20995	7590	02/17/2021	EXAMINER	
KNOBBE MARTENS OLSON & BEAR LLP			FARDANESH, MARJAN	
2040 MAIN STREET				
FOURTEENTH FLOOR				
IRVINE, CA 92614				

ART UNIT	PAPER NUMBER
3791	

NOTIFICATION DATE	DELIVERY MODE
02/17/2021	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

efiling@knobbe.com

jayna.cartee@knobbe.com

<i>Applicant-Initiated Interview Summary</i>	Application No. 17/028,655	Applicant(s) Smith et al.		
	Examiner MARJAN FARDANESH	Art Unit 3791	AIA (First Inventor to File) Status No	Page 1 of 1

All Participants (applicant, applicants representative, PTO personnel)	Title	Type
MARJAN FARDANESH	Examiner	Telephonic
David Grant	Attorney of Record	

Date of Interview: 04 February 2021

Issues Discussed:

35 U.S.C. 103

Applicant provided brief summary of the invention and discussed how their invention is different from Schulz reference. Examiner indicated that the differentiating aspect of top of the shoe box having only one opening is not claimed. Applicant agreed to take the discussions into consideration while filing a formal response.

☒ Attachment

/MARJAN FARDANESH/ Examiner, Art Unit 3791	
<p>Applicant is reminded that a complete written statement as to the substance of the interview must be made of record in the application file. It is the applicants responsibility to provide the written statement, unless the interview was initiated by the Examiner and the Examiner has indicated that a written summary will be provided. See MPEP 713.04</p> <p>Please further see: MPEP 713.04 Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews, paragraph (b) 37 CFR § 1.2 Business to be transacted in writing</p>	

Applicant recordation instructions: The formal written reply to the last Office action must include the substance of the interview. (See MPEP section 713.04). If a reply to the last Office action has already been filed, applicant is given a non-extendable period of the longer of one month or thirty days from this interview date, or the mailing date of this interview summary form, whichever is later, to file a statement of the substance of the interview.

Examiner recordation instructions: Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
 United States Patent and Trademark Office
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 P.O. Box 1450
 Alexandria, Virginia 22313-1450
 www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

20995 7590 03/03/2021
 KNOBBE MARTENS OLSON & BEAR LLP
 2040 MAIN STREET
 FOURTEENTH FLOOR
 IRVINE, CA 92614

EXAMINER

FARDANESH, MARJAN

ART UNIT

PAPER NUMBER

3791

DATE MAILED: 03/03/2021

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/028,655	09/22/2020	Robert A. Smith	MLR.002C6	3736

TITLE OF INVENTION: MULTIPLE WAVELENGTH SENSOR EMITTERS

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	\$1200	\$0.00	\$0.00	\$1200	06/03/2021

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 1/2 the amount of undiscounted fees, and micro entity fees are 1/2 the amount of small entity fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Maintenance fees are due in utility patents issuing on applications filed on or after Dec. 12, 1980. It is patentee's responsibility to ensure timely payment of maintenance fees when due. More information is available at www.uspto.gov/PatentMaintenanceFees.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), by mail or fax, or via EFS-Web.

By mail, send to: Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

By fax, send to: (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

20995 7590 03/03/2021
KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being transmitted to the USPTO via EFS-Web or by facsimile to (571) 273-2885, on the date below.

(Typed or printed name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/028.655	09/22/2020	Robert A. Smith	MLR.002C6	3736

TITLE OF INVENTION: MULTIPLE WAVELENGTH SENSOR EMITTERS

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	\$1200	\$0.00	\$0.00	\$1200	06/03/2021

EXAMINER	ART UNIT	CLASS-SUBCLASS
FARDANESH, MARJAN	3791	600-324000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-09 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,

(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 _____

2 _____

3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. Fees submitted: ☐ Issue Fee ☐ Publication Fee (if required) ☐ Advance Order - # of Copies _____

4b. Method of Payment: (Please first reapply any previously paid fee shown above)

☐ Electronic Payment via EFS-Web ☐ Enclosed check ☐ Non-electronic payment by credit card (Attach form PTO-2038)

☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No. _____

5. Change in Entity Status (from status indicated above)

☐ Applicant certifying micro entity status. See 37 CFR 1.29

☐ Applicant asserting small entity status. See 37 CFR 1.27

☐ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____

Date _____

Typed or printed name _____

Registration No. _____



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/028,655	09/22/2020	Robert A. Smith	MLR.002C6	3736
20995	7590	03/03/2021	EXAMINER	
KNOBBE MARTENS OLSON & BEAR LLP			FARDANESH, MARJAN	
2040 MAIN STREET			ART UNIT	
FOURTEENTH FLOOR			PAPER NUMBER	
IRVINE, CA 92614			3791	
DATE MAILED: 03/03/2021				

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
 (Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Notice of Allowability	Application No. 17/028,655	Applicant(s) Smith et al.	
	Examiner MARJAN FARDANESH	Art Unit 3791	AIA (FITF) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to amendments filed on 02/09/2021.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

3. ☒ The allowed claim(s) is/are 21-49. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a) ☐ All b) ☐ Some *c) ☐ None of the:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____.

3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. <input type="checkbox"/> Notice of References Cited (PTO-892) 2. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date <u>02/09/2021</u> . 3. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material _____. 4. <input type="checkbox"/> Interview Summary (PTO-413), Paper No./Mail Date. _____.	5. <input type="checkbox"/> Examiner's Amendment/Comment 6. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance 7. <input type="checkbox"/> Other _____.
--	--

/MARJAN FARDANESH/ Examiner, Art Unit 3791	/ERIC F WINAKUR/ Primary Examiner, Art Unit 3791
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Application/Control Number: 17/028,655
Art Unit: 3791

Page 2

DETAILED ACTION

Notice of Pre-AIA or AIA Status

1. The present application is being examined under the pre-AIA first to invent provisions.

Reasons for Allowance

2. The following is an examiner's statement of reasons for allowance: Schulz et al. (USPN 6,580,086-previously cited) discloses a physiological monitoring device comprising: one or more LEDs recessed into a cavity, the one or more LEDs configured to emit light of at least three different wavelengths (Col.5 line 50-Col.6 line 60); at least one detector configured to detect at least a portion of the light emitted from the one or more after at least a portion of the light has been attenuated by tissue, the at least one detector configured to output at least one signal responsive to the detected light (Col.5 line 50-Col.6 line 60); an electromagnetic interference shield positioned between the LEDs and the at least one detector (Col. 12 line 20-Col. 13 line 3); and a processor configured to receive and process one or more signals responsive to the outputted at least one signal and determine a physiological parameter of a user responsive to the one or more signals (Col. 12 line 20-Col. 13 line 3). While Schulz et al. discloses one or more LEDs, Schulz fails to disclose at least three LEDs. Thomas et al. discloses reliable non-invasive measurement of blood gases including light emitting diodes and detector (figure 48, Col.28 line 50-Col.29 line 60). Therefore, it would have been obvious to one of ordinary skills in the art at the time the invention was made to incorporate the several light sources of Thomas et al. into the device of Schulz et al., since such modification provides several light sources in order to obtain multiple physiological parameters.

Application/Control Number: 17/028,655
Art Unit: 3791

Page 3

However, the combination of Schulz et al. in view of Thomas et al. fails to disclose a light block surrounding the at least one detector, the light block comprising a shoebox structure configured to recess the at least one detector into the shoebox structure, wherein the shoebox structure is formed of a black material, the shoebox structure further comprising a window on a top portion of the shoebox structure, the window comprising an area smaller than a detection surface area of the at least one detector, in combination with remaining claimed features.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARJAN FARDANESH whose telephone number is (571)270-5508. The examiner can normally be reached on Monday-Friday 9:00-17:00.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at <http://www.uspto.gov/interviewpractice>.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jacqueline Cheng can be reached on (571)272-5596. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Application/Control Number: 17/028,655
Art Unit: 3791

Page 4

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <https://ppair-my.uspto.gov/pair/PrivatePair>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ERIC F WINAKUR/
Primary Examiner, Art Unit 3791

/MARJAN FARDANESH/
Examiner, Art Unit 3791

EXHIBIT 20

US006580086B1

(12) **United States Patent**
Schulz et al.

(10) **Patent No.:** **US 6,580,086 B1**
(45) **Date of Patent:** **Jun. 17, 2003**

(54) **SHIELDED OPTICAL PROBE AND METHOD**

JP 11053662 2/1999
JP 11185193 7/1999
WO 97/23159 7/1997

(75) Inventors: **Christian E. Schulz**, Rancho Santa Margarita; **Eugene E. Mason**, La Mirada; **Ammar Al Ali**, Tustin, all of CA (US)

OTHER PUBLICATIONS

(73) Assignee: **Masimo Corporation**, Irvine, CA (US)

“Pulse Oximeter 3 and 3i,” Minolta, <http://www.minoltausa.com/eprise/main/MinoltaUSA/MUSACContent/ISD/De-tailPage?canam>, 1 page downloaded and printed from the World Wide Web on Aug. 7, 2002.

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

“PULSOX Sensors,” Minolta, <http://www.pulsoxminolta.ch/probesl.htm>, 4 pages downloaded and printed from the World Wide Web on Aug. 7, 2002.

(21) Appl. No.: **09/420,544**

* cited by examiner

(22) Filed: **Oct. 19, 1999**

Primary Examiner—Que T. Le

Related U.S. Application Data

(74) Attorney, Agent, or Firm—Knobbe, Martens, Olson & Bear, LLP

(60) Provisional application No. 60/150,922, filed on Aug. 26, 1999.

(57) **ABSTRACT**

(51) Int. Cl.⁷ **G06K 15/00**
(52) U.S. Cl. **250/557**; 250/461.2; 128/633
(58) Field of Search 250/557, 227.14, 250/221, 214.1, 573, 461.2, 338.5, 239; 356/41, 39; 128/633, 665–667

An optical probe, which is particularly suited to for use in measurements on tissue material of a patient. In one embodiment, the probe comprises upper and lower housing elements incorporating a light energy source and corresponding detector. The tissue material of the patient is disposed between the upper and lower housing elements such that the light energy emitted by the source passes through the tissue material to the detector. A plurality of light shields are attached to one or both of the housing elements to reduce the amount of ambient and reflected light reaching the detector. Additionally, various portions of the upper and lower housing elements and shields utilize light absorbent coloration and/or coatings which further mitigate the effects of undesired ambient and reflected light, thereby reducing noise generated within the instrument and increasing its accuracy. In one embodiment, the light shields are made removable from the optical probe, thereby facilitating replacement. A circuit for monitoring the condition of the probe, and indicating when replacement of the probe is desirable, is also disclosed.

(56) **References Cited**

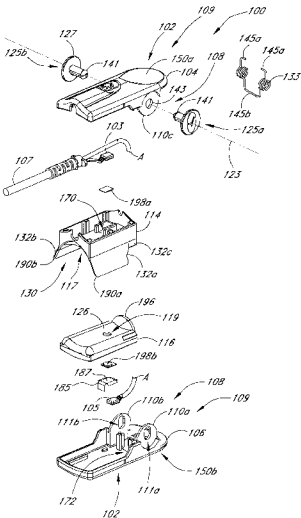
U.S. PATENT DOCUMENTS

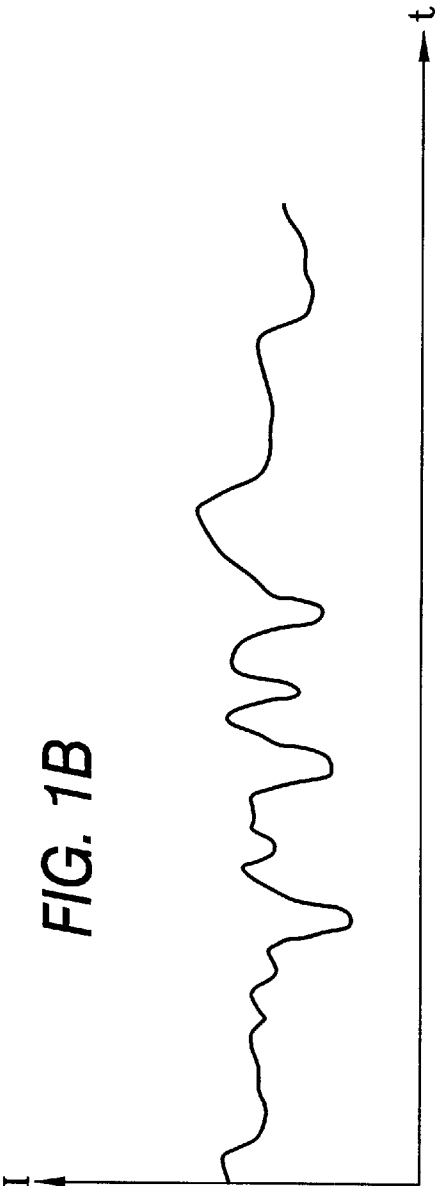
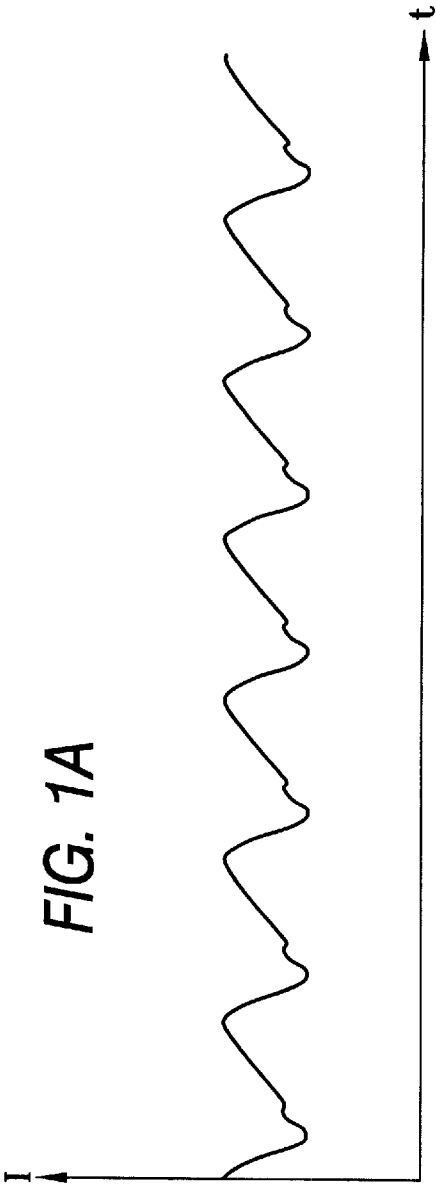
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5,490,523 A * 2/1996 Isaacson et al. 128/633
5,939,609 A 8/1999 Knapp et al. 73/1.01

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EP 481 612 10/1990
EP 745 348 12/1996
EP 0 832 598 A2 4/1998
JP 02017462 1/1990
JP 10314149 12/1998

36 Claims, 11 Drawing Sheets





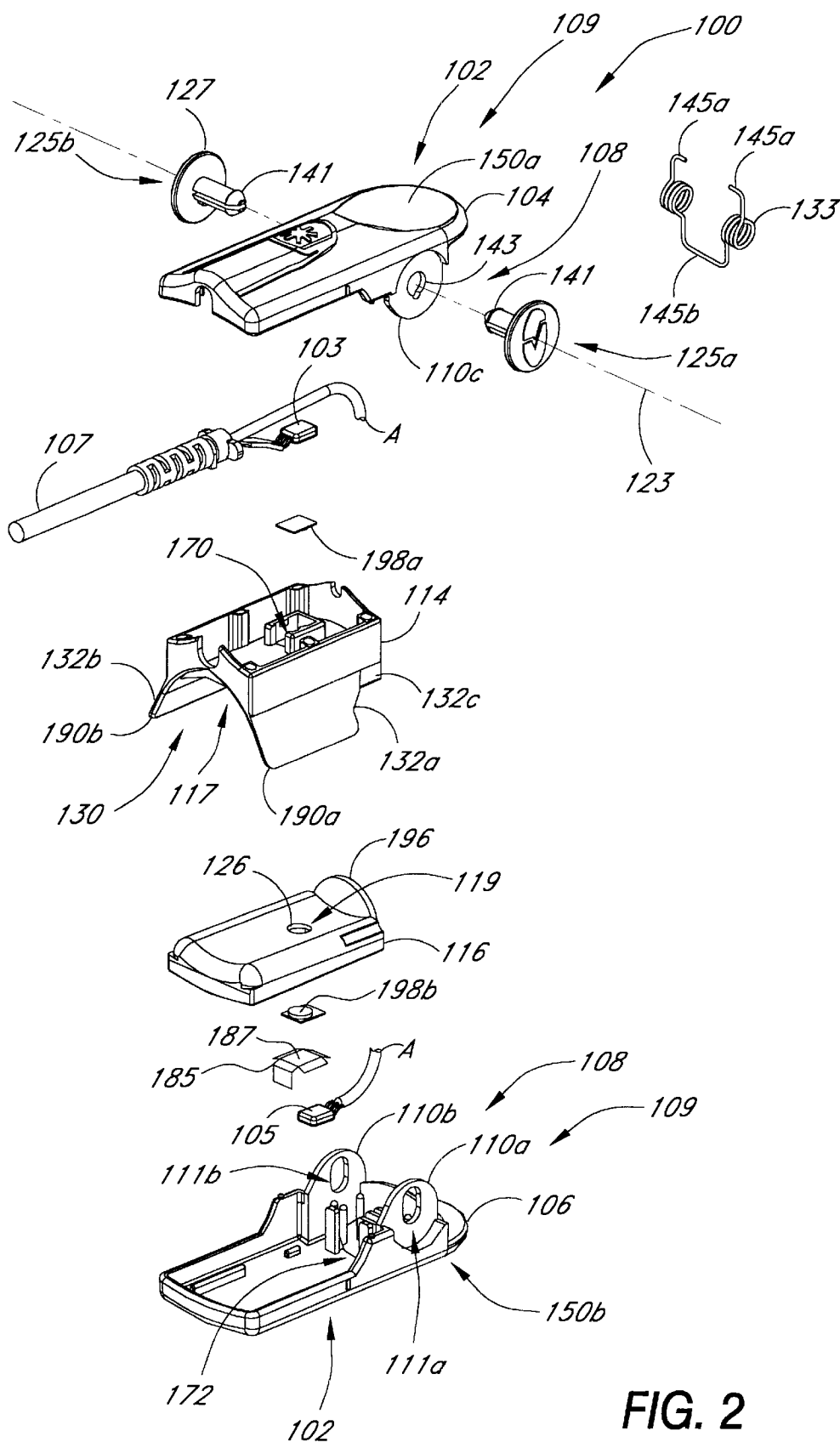


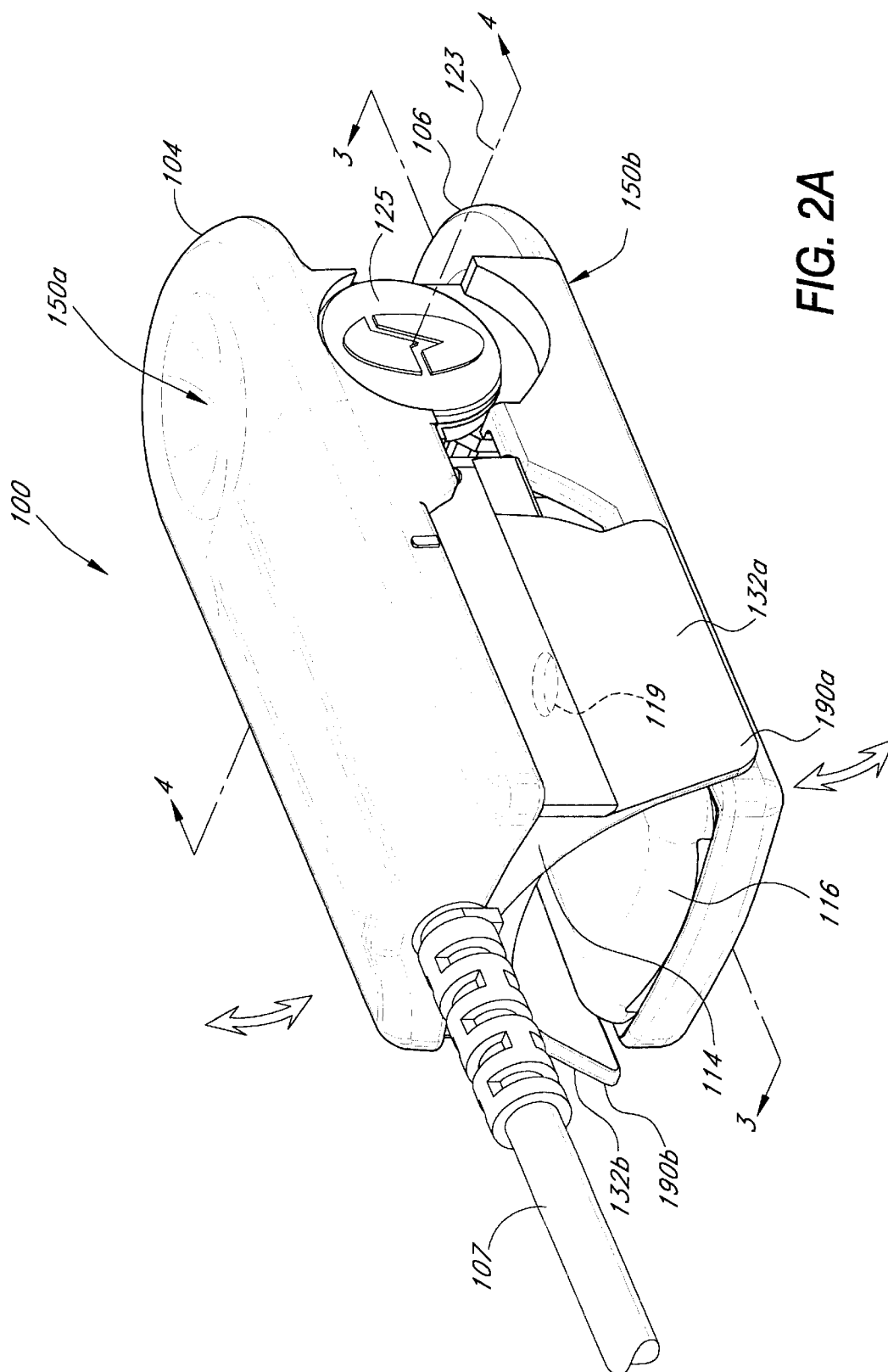
FIG. 2

U.S. Patent

Jun. 17, 2003

Sheet 3 of 11

US 6,580,086 B1



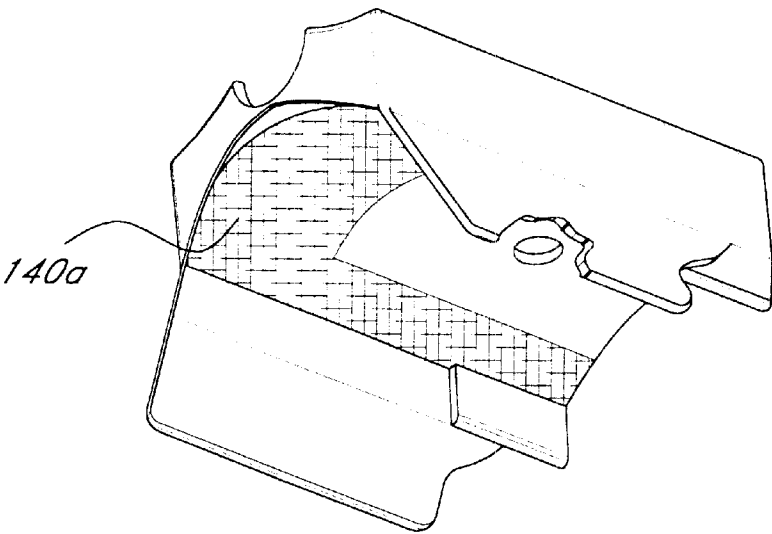


FIG. 2B

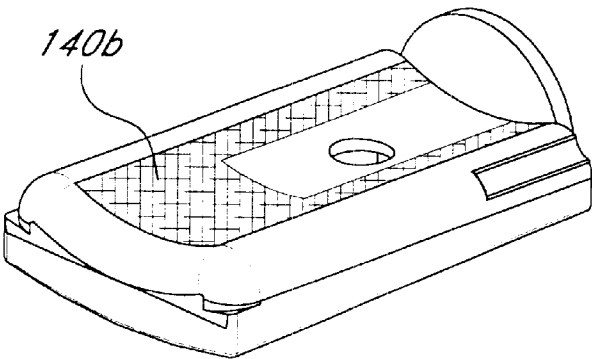


FIG. 2C

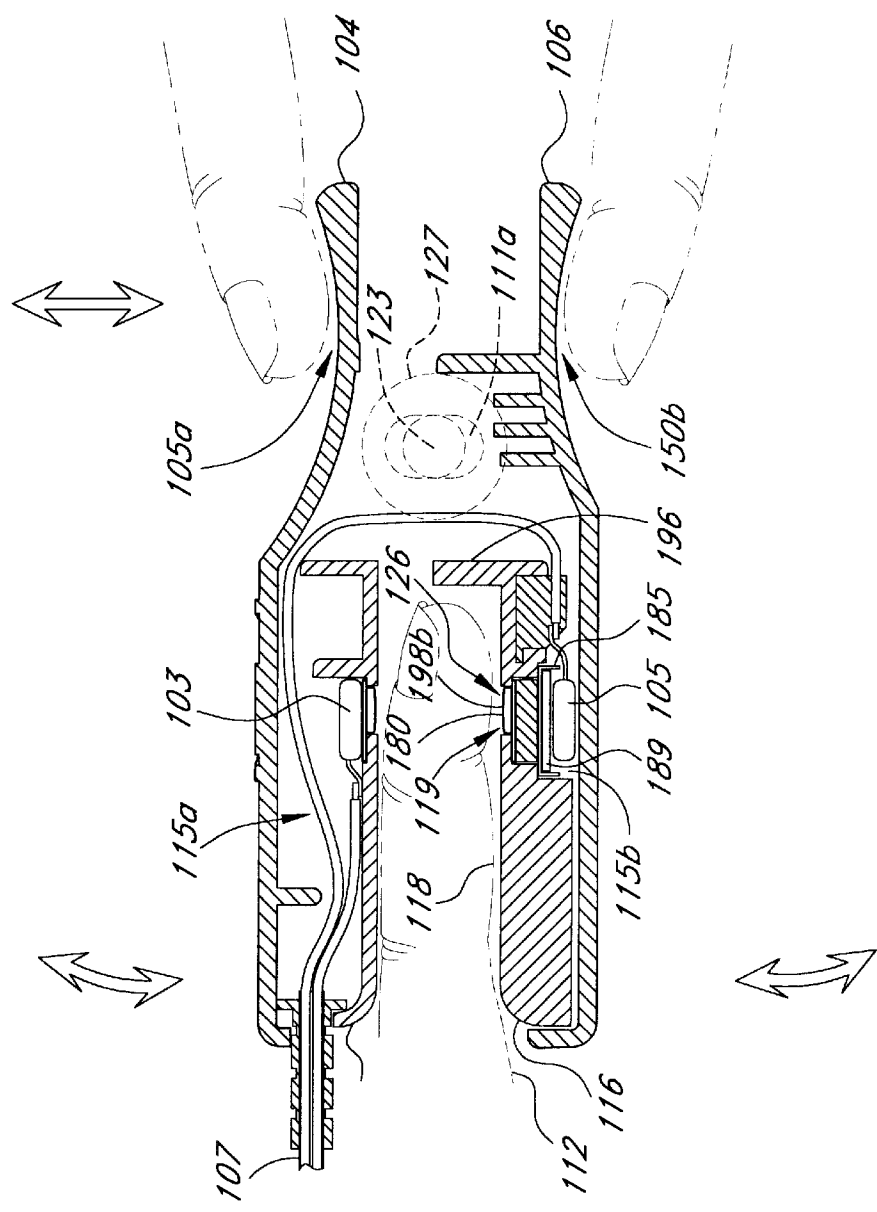


FIG. 3

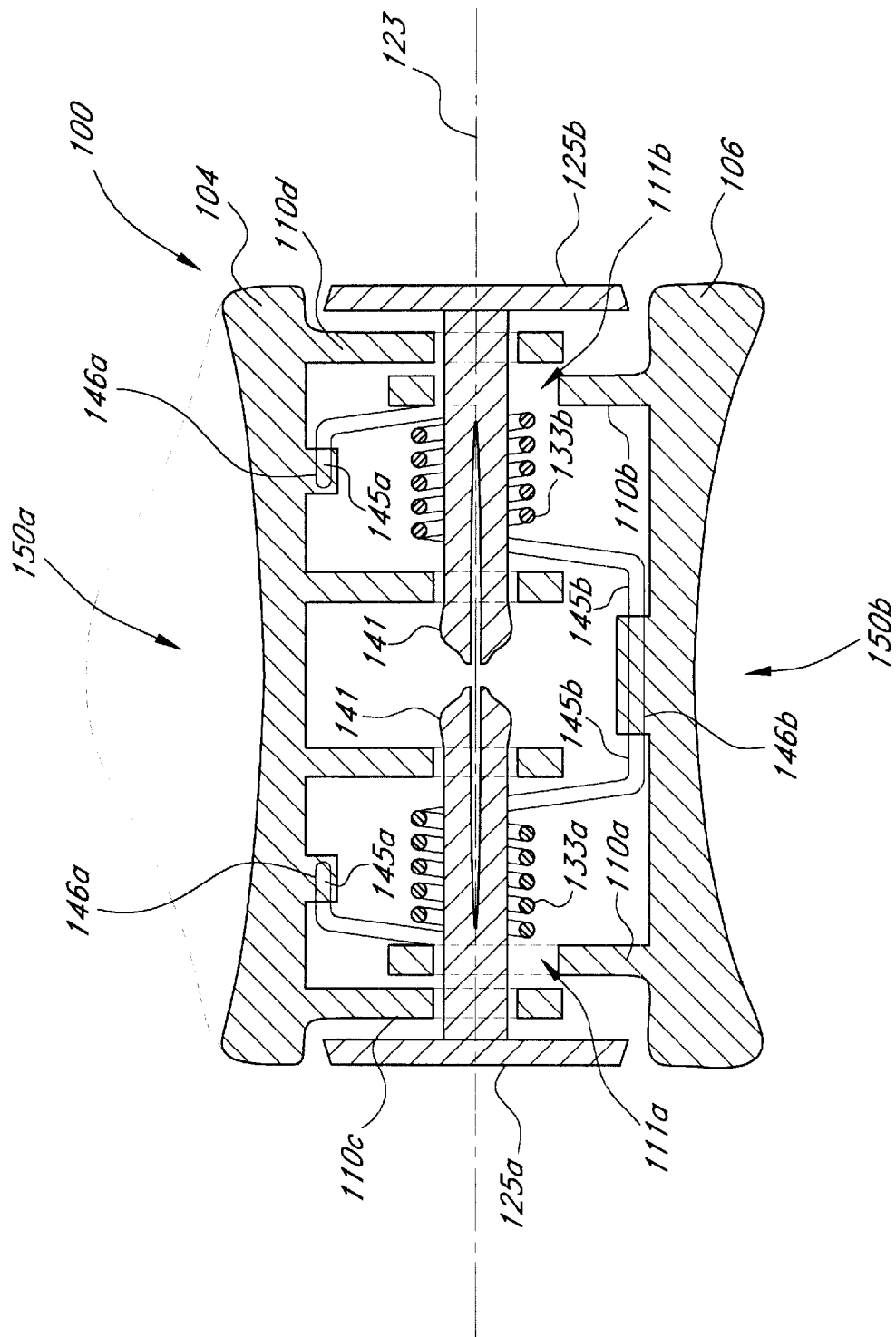
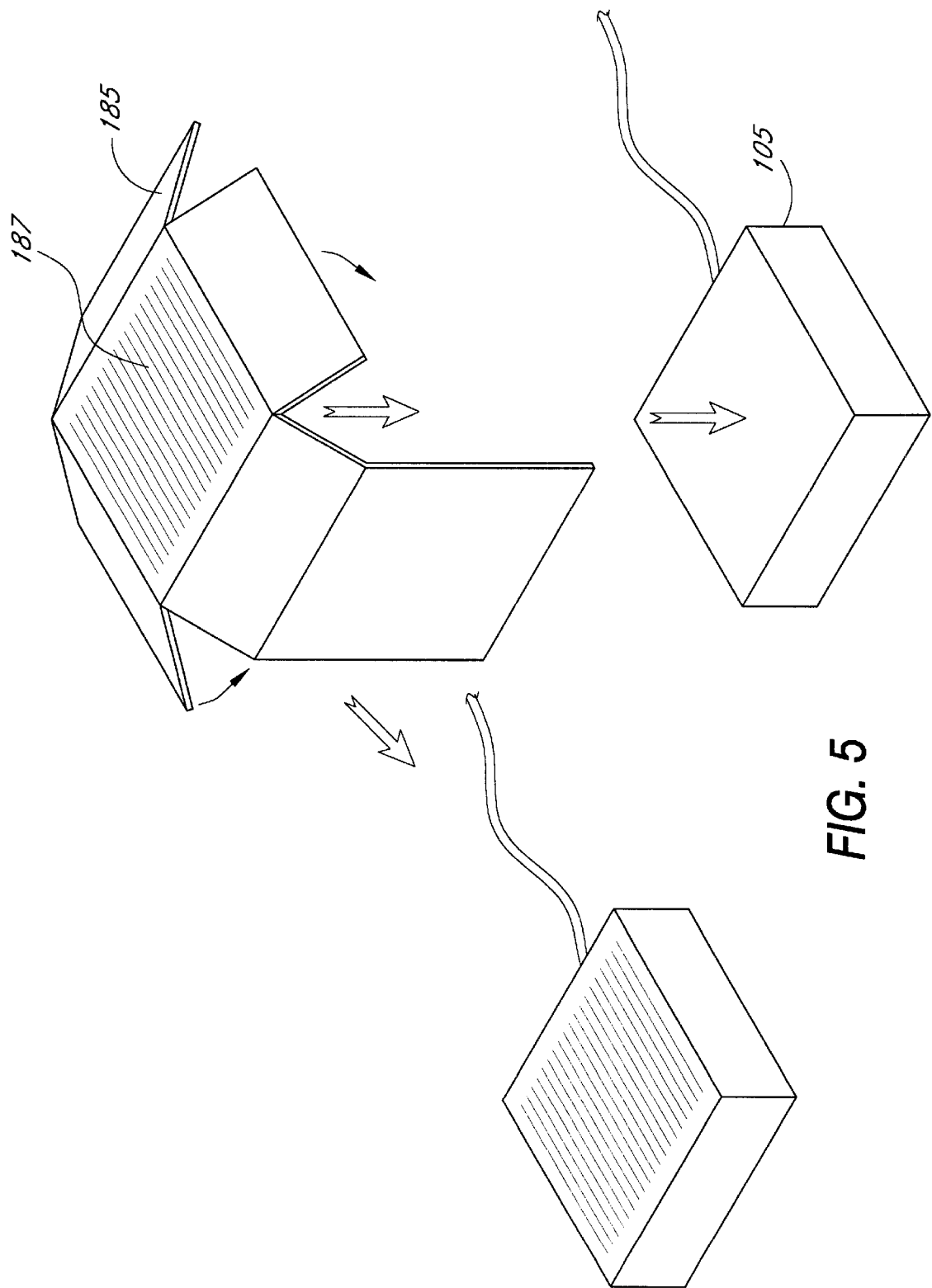
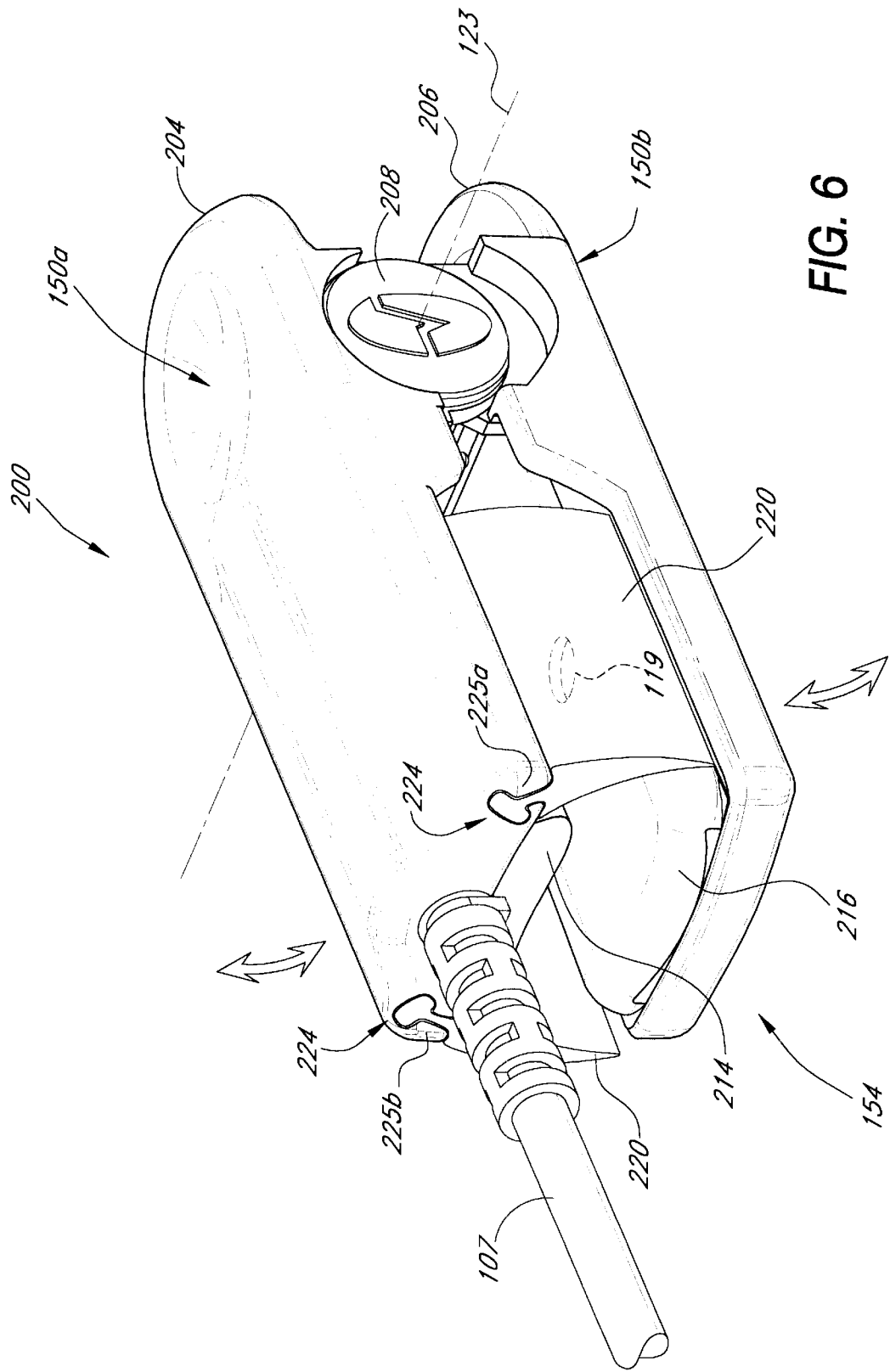


FIG. 4





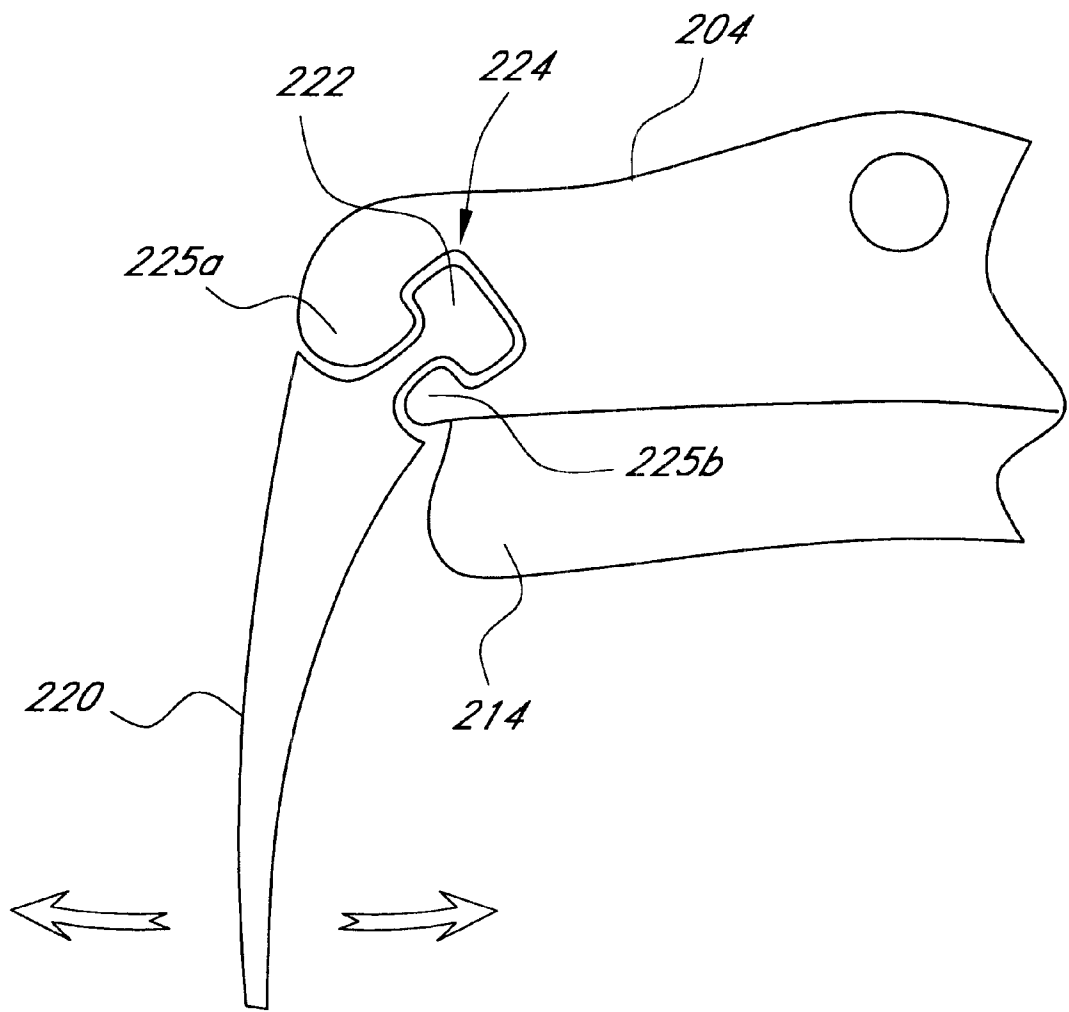
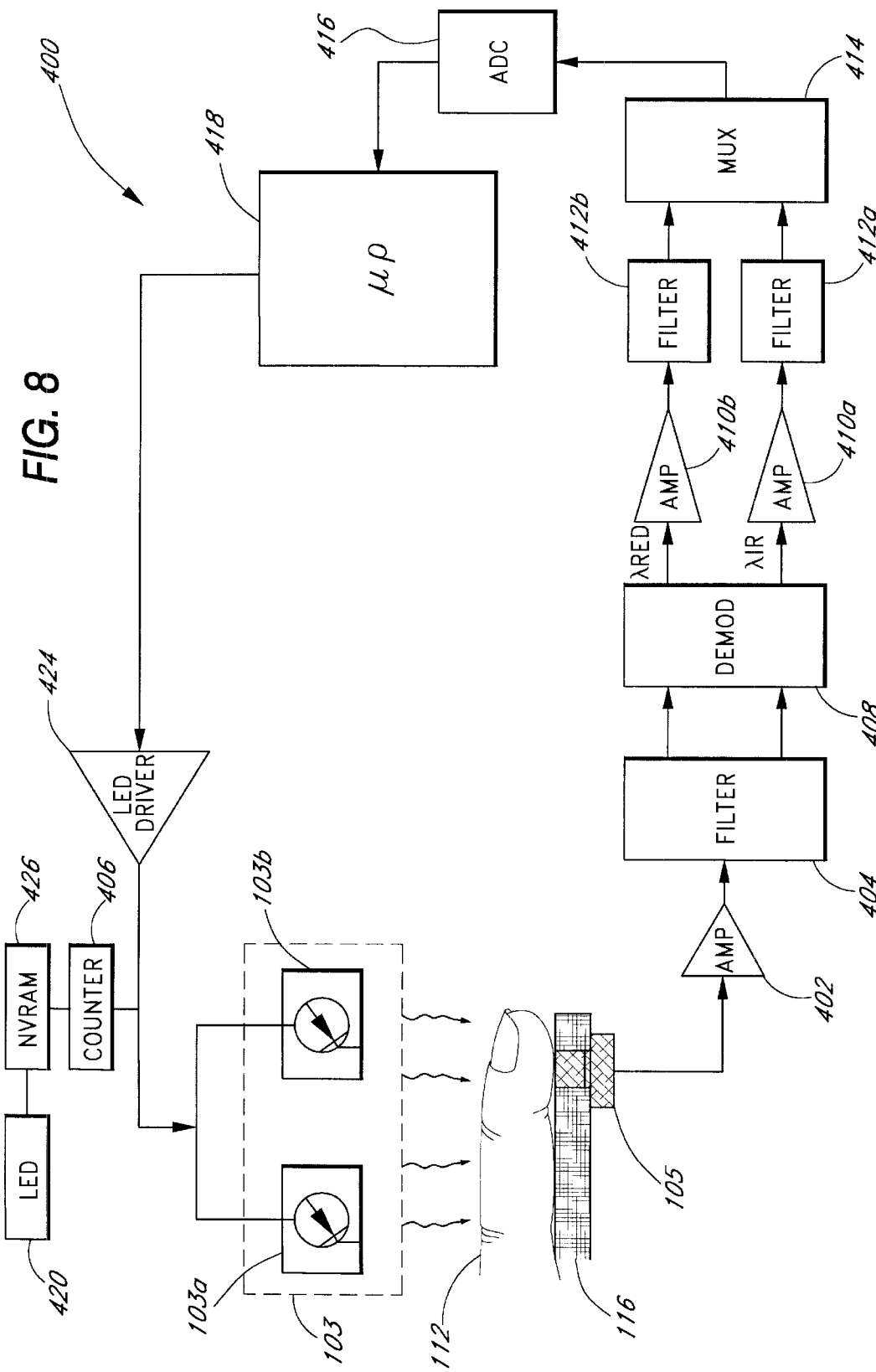


FIG. 6A



SHIELDED OPTICAL PROBE AND METHOD

This application claims the benefit of earlier filed provisional patent application Ser. No. 60/150,922, filed Aug. 26, 1999.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to low-noise optical probes which may be used to sense optical energy passed through or reflected from a medium to determine the characteristics of the medium.

2. Description of the Related Art

The physical characteristics of a given medium may often be determined by transmitting electromagnetic or acoustic energy through, or reflected energy from, portions of the medium. For example, in the context of medical diagnosis, light or sound energy may be directed onto a portion of a patient's body, and the fraction of that energy transmitted through (or reflected by) the patient's body measured to determine information about the various physical attributes of the patient. This type of non-invasive measurement is both more comfortable for and less deleterious to the patient than invasive techniques, and can generally be performed more quickly.

Non-invasive physiological monitoring of bodily function is often required. For example, during surgery, blood oxygen saturation (oximetry) is often continuously monitored. Measurements such as these are often performed with non-invasive techniques where assessments are made by measuring the ratio of incident to transmitted (or reflected) light through an accessible part of the body such as a finger or an earlobe. A typical transmissive non-invasive monitoring device includes a light source such as a light-emitting diode (LED) placed on one side of the body part, while a photodetector is placed on an opposite side of the body part. Light energy generated by the LED is transmitted through the tissue, blood, and other portions of the body part, and detected by the photodetector on the other side. Alternatively, in a reflective device, the detector is placed on the same side of the body part as the light source, and the amount of light energy reflected by the body part measured.

The transmission of optical energy passing through the body is strongly dependent on the thickness of the material through which the light passes (the optical path length). Many portions of a patient's body are typically soft and compressible. For example, a finger comprises a number of components including skin, muscle, tissue, bone, and blood. Although the bone is relatively incompressible, the tissue, muscle, and skin are easily compressible or deformed with pressure applied to the finger, as often occurs when the finger is bent. Thus, if optical energy is made incident on a patient's finger, and the patient moves in a manner which distorts or compresses the finger, the optical properties, including optical path length, may change. Since a patient generally moves in an erratic fashion, the compression of the finger is erratic and unpredictable. This causes the change in optical path length to be erratic, making the absorption of incident light energy erratic, and resulting in a measured signal which can be difficult to interpret. Similarly, movement of the patient during a reflective measurement can dramatically affect the quality of the signal obtained therefrom.

In addition to the typical problem of patient movement, the presence of unwanted ambient and/or reflected light energy interferes with the measurement of the intensity of

the light transmitted through or reflected by the body part. Optical transmission/reflection systems as described above utilize a light energy detector which measures, inter alia, the intensity of light transmitted to or reflected from the body part being analyzed. Since ambient light incident on the detector affects the intensity measurement, noise or error is introduced into the measured signal by such ambient light. Similarly, light generated by the light source within the measuring device (typically, an LED) which is not transmitted through or reflected by the body part under examination will also result in signal error if such light is received by the detector. These "secondary" reflections arise when light emitted by the light source is reflected by structures within the optical probe onto the detector. Accordingly, to increase the accuracy of the measurement process, both ambient light and "secondary" reflections from the light source should be mitigated.

FIG. 1a illustrates an ideal signal waveform obtained from an optical probe system. FIG. 1b illustrates an actual spectra obtained from a typical optical probes not corrected for the effects of patient motion or ambient/reflected light. Note the significant increase in noise (and resulting loss of signal clarity) in FIG. 1b due to these effects.

Prior optical probes have successfully addressed the issue of ease of use and patient motion during measurement. See, for example, U.S. Pat. No. 5,638,818 entitled "Low Noise Optical Probe," assigned to the Applicant herein, which discloses a system utilizing a chamber which isolates that portion of the patient's tissue under examination from compression or movement by the patient. The device is attached to the finger of a patient, thereby readily and accurately positioning the tissue of the patient's finger over the chamber.

However, attempts at limiting the effects of ambient and "secondary" reflected light have been less successful, not due to their ineffectiveness, but rather due to their obtrusiveness and relative complexity of use. A need exists, especially in the health care context, for a simple, fast, unobtrusive, and largely error-free means of non-invasive measurement of a patient's physical parameters. Especially critical is the attribute that such means be easily adapted to a variety of different patient types and characteristics with little or no adjustment, as is the device disclosed in the aforementioned patent. Prior art methods of mitigating ambient and reflected light interference have involved coverings or shrouds which substantially envelop the optical probe and tissue, thereby requiring substantial sizing and adjustment of the covering for each different patient being measured. Another disadvantage of such methods is that the placement of the patient's appendage (such as a finger) in relation to the light source and detector can not be reliably verified by the person administering the measurement unless the probe is first placed on the appendage, and the covering installed thereafter, or alternatively, unless the patient is queried. This necessitates additional time and effort on the part of the patient and the person making the measurement.

Another factor relating to the efficacy of an optical probe is force distribution on the body part or tissue material being measured. Specifically, if force is distributed on the tissue material being measured unevenly or disproportionately, varying degrees of compression of the tissue may result, thereby producing a broader range of optical path lengths in the region of the light source and detector. Furthermore, if the force that the probe exerts on the tissue material is highly localized, the ability of the patient to move the tissue material with respect to the source/detector is enhanced, thereby leading to potentially increased noise levels within the signal generated by the probe.

Yet another consideration relating to non-invasive optical probe measurement involves cost. In recent times, the demand has increased significantly for both disposable and reusable optical probes which are suitably constructed to provide accurate, low-noise measurements. The aforementioned prior art methods of attenuating ambient and reflected light employing coverings or shrouds carry with them a significant cost, especially if the probe (or components thereof) must be replaced on a frequent basis. Therefore, in many applications, it would be useful to have a low-cost reusable optical probe capable of attenuating ambient and reflected light, with only the degradable components being easily and cost-effectively replaced as required, without necessitating the replacement of the entire probe. Similarly, it would be useful to have a disposable probe capable of attenuating ambient and reflected light, which could be routinely replaced in its entirety a cost-effective manner.

Finally, existing optical probes do not include an easy to use and reliable means for determining when to replace the probe. At present, the probe operator or health care provider must keep a record or log of the date of installation of a given probe, and replace it at a given periodicity or simply replace the probe when it seems worn out. This approach is problematic, however, not only from the standpoint of additional time and effort consumed in maintaining the record, but more significantly from the perspective that the measurement of installed time is not necessarily representative of the wear on the probe. For example, two probes installed on the same date may experience significantly different levels of wear, depending on the level of use. Alternatively, the operator could keep a log of usage, but this is too burdensome and time consuming.

Based on the foregoing, a need exists for an improved low-noise optical probe which (i) is simple in design and easy to use under a variety of different operating conditions; (ii) is capable of attenuating ambient and reflected light without necessitating probe adjustment or fitting to each different patient; (iii) is capable of alerting the operator when replacement is required; and (iv) is cost effective. Such an improved probe would also ideally shield against noise caused by electromagnetic interference (EMI).

SUMMARY OF THE INVENTION

The present invention satisfies the foregoing needs by providing an improved optical probe for use in non-invasive energy absorption or reflection measurements, as well as a method of using the same.

In a first aspect of the invention, an improved shielded optical probe assembly is disclosed which incorporates a light energy source and light energy detector embedded within a multi-part housing adapted to receive and clamp onto tissue material from the patient. When the probe is operating, light energy is directed from the light energy source through a first aperture formed within a first element of the housing and onto the tissue material of the patient, which is received within the probe. A portion of this light is transmitted through (or reflected from) the tissue material onto the detector via a second aperture. In this fashion, a light generated by the light source and transmitted through or reflected from the tissue material at a localized point is received by the detector. A light shield is fitted to the housing so as to partially surround the tissue material when it is received within the housing, thereby attenuating ambient light incident on the optical probe. In one embodiment, the light shield is made removable in order to facilitate its replacement after degradation and wear. Additionally, por-

tions of the shield and housing are colored and/or coated such that light incident on these portions is absorbed or attenuated. The foregoing light attenuation features act to reduce the effects of noise induced within the detector (and associated processing circuitry) due to light energy not transmitted directly through or reflected from the tissue material from the light source. The probe is also optionally fitted with a diffraction grating and Faraday shield to mitigate the effects of unwanted optical modes and electromagnetic interference on probe accuracy.

In a second aspect of the invention, the foregoing optical probe includes a mechanism for equalizing the force applied to the tissue of the patient when the probe is clamped thereon. In one embodiment, a series of elongated apertures each receive hinge pins which are biased apart by springs wound around the axis of the pins. When the housing elements of the probe are grasped and compressed together by the user, the hinge pins are forced against one edge of the elongated apertures, thereby providing a fulcrum for opening the probe. After the probe is opened, and the patient's finger inserted, the compressing force is removed, thereby allowing the housing elements to clamp onto the finger. As the compression force is removed, the spring bias allows the previously compressed ends of the housing elements apart, and urging the pins to the opposite edge of the elongated apertures, and "leveling" the housing elements into a more parallel orientation. This parallel orientation distributes force on the patient's finger more evenly.

In a third aspect of the invention, a monitoring device is disclosed which is integrated with the optical probe circuitry in order to assist the operator in determining when to replace the probe. In one embodiment, the monitoring device is a counter which counts the number of electrical pulses generated by the detector circuitry, and correlates this number to the time of actual probe operation and percent of useful lifetime. A light emitting diode visible on the exterior of the probe is used to alert the operator to the need for probe replacement.

In another aspect of the invention, a method of measuring the amount of light transmitted or reflected by the tissue material of a patient using the aforementioned optical probe is disclosed. In one embodiment of the method, the tissue material is inserted into the shielded probe housing, and light generated by the light source of the probe is transmitted via the first aperture into the tissue material. Light energy transmitted (or reflected) by the tissue material is then detected by the detector via the second aperture, and a signal relating to the intensity of the detector generated. Ambient light incident on the probe, and light generated by the light source and scattered off components other than the tissue material, are attenuated or absorbed by the shield and absorptive coating(s) during detection and signal generation in order to reduce any noise component associated therewith. The operating time of the probe is also counted in order to monitor probe remaining lifetime.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1a illustrates an ideal optical transmittance signal that would be measured by a typical prior art optical probe when utilized for blood oximetry.

FIG. 1b illustrates a non-ideal optical transmittance signal measured by a typical prior art optical probe when utilized for blood oximetry.

FIG. 2 is an exploded perspective view of a first embodiment of the optical probe of the present invention, configured to measure optical transmission.

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FIG. 2a is a perspective view of the optical probe of FIG. 2 when assembled.

FIG. 2b is a perspective view of an upper support surface element of the optical probe of the present invention with a nonreflecting portion depicted with shading.

FIG. 2c is a perspective view of the lower support surface element shown in FIG. 2 with a nonreflecting portion depicted with shading.

FIG. 3 is a cross-sectional view of the optical probe of FIG. 2 when assembled, taken along line 3—3 thereof.

FIG. 4 is a cross-sectional view of the optical probe of FIG. 2 when assembled, taken along line 4—4 thereof.

FIG. 5 is a perspective view of the detector shield of the present invention, shown during assembly.

FIG. 6 is a perspective view of a second embodiment of the optical probe of the present invention configured to measure optical transmission.

FIG. 6a is a detail plan view of the removable shield elements and channels of the optical probe of FIG. 6.

FIG. 7 is a cross-sectional view of a third embodiment of the optical probe of the present invention configured to measure optical reflectance.

FIG. 8 is a block diagram illustrating one embodiment of a monitoring device circuit according to the present invention.

DETAILED DESCRIPTION OF THE INVENTION

The invention is described in detail below with reference to the figures, wherein like elements are referenced with like numerals throughout.

It is noted that the term “tissue material” as used herein includes, without limitation, the skin, tissue, blood, cartilage, ligaments, tendons, muscle, or bone of a given portion of a patient’s body, such as the distal end of a finger, or any portion thereof.

The term “light energy” as used herein refers to any type of electromagnetic radiation or energy, whether comprised of a narrow, discrete frequency or multiple frequencies. Examples of light energy include visible light, infrared radiation, and ultraviolet radiation. While described as an “optical” probe, the invention disclosed herein may also feasibly be used in conjunction with other forms of energy or radiation, whether optically visible or not.

As shown in FIGS. 2 and 3, a first embodiment of the improved optical probe of the present invention is described. As shown in FIGS. 2 and 3, the present embodiment of the probe 100 generally comprises a two-piece housing 102, a light energy source 103, and a light energy detector 105, and an electrical supply and signal cable 107. The housing 102 consists of a first (upper) housing element 104 and a second (lower) housing element 106, which are rotatably attached to one another via a pivot element 108. The light source 103 is disposed within the upper housing element 104, while the detector is disposed within the lower housing element 106. The housing 102 of the present embodiment is adapted to receive the distal end of a finger 112 as shown in FIG. 3, with the “upper” housing element 104 engaging the upper surface 113 of the finger 112, and the “lower” housing element 106 engaging the lower surface 118 of the finger 112. It will be recognized, however, that the probe 100 may be used in any orientation, such as with the first housing element 104 being located below the second housing element 106. Furthermore, the light source 103 may alternatively be placed in the lower housing element 106, and the detector in

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the upper housing element 104 if desired, subject to modification of other probe components as described further below. It is also noted that while the following discussion describes a series of exemplary embodiments based on measuring the optical characteristics of a finger 112, the present invention may be adapted for use with any number of other body parts, such as earlobes or loose skin, with equal success. Hence, the specific embodiments described herein are merely illustrative of the broader invention.

The first and second housing elements 104, 106 of the probe 100 of FIGS. 2 and 3 are generally rectangular in form, with the pivot element 108 being disposed near a common end 109 of each of the elongate housing elements 104, 106. The housing elements 104, 106 are in the present embodiment formed from an opaque plastic using an injection molding process of the type well known in the polymer sciences, although other materials and formation techniques may be used. The first housing element 104 includes a monitoring light emitting diode (LED) 426 visible to the operator, as is described in greater detail below with respect to FIG. 8. The first and second housing elements 104, 106 further each include support surface elements 114, 116, and one or more pairs of vertical risers 110a–110d with pin apertures 111a, 111b, the latter which are used to form the basis of the pivot element 108. The two housing elements 104, 106 are biased around the rotational axis 123 of the pivot element 108 by a biasing element, in this case a hinge spring 133 as described further below.

As shown in FIG. 2, the pivot element 108 of the present embodiment comprises a hinge, and includes the aforementioned vertical risers 110a–110d, two hinge pins 125a, 125b, and biasing spring 133 located along the central axis 123 of the hinge pins 125a, 125b. The hinge pins 125a, 125b each include an outward retaining element 127, and are of a “split pin” design such that a ridge 141 located on the distal end 144 of each pin 125 engages a corresponding edge 143 of the respective interior vertical riser 110c, 110d of the upper housing element 104 when each pin 125 is fully received within the probe 100, as shown in FIG. 4. This arrangement, specifically the ridges 141 of the pins 125 engaging the edges 143 of their respective vertical risers 110 under an outward biasing force generated by the split in the pin, permits the pins 125 to be readily “snapped” into the apertures 111 within the vertical risers 110, thereby forming a hinge with pivot or rotational axis for the upper and lower housing elements 104, 106. The biasing spring 133 fits around the pins 125a, 125b as shown in FIG. 4, the two free ends 145a, and the connecting section 1456 being received with respective holders 146a, 146b formed within the interior surfaces of the upper and lower housing elements 104, 106, respectively. Using this arrangement, the biasing spring 133 is preloaded (i.e., partially wound) so as to bias the upper housing element 104 against the lower housing element 106. A pair of finger recesses 150a, 150b are formed within the outward portion of each of the housing elements 104, 106, at a location between the common end 109 of each housing element and the pivot axis 123, thereby permitting the user to grasp the probe 100 between his or her fingers using the recesses 150a, 150b and separate the probe housing elements 104, 106 by applying force counter to the spring biasing force. In this fashion, the user simply grasps the probe 100, opens it by applying a light force with the grasping fingers, and inserts the distal end of the patient’s finger 112 into the opened end 154 of the probe.

As depicted in FIG. 2, the pin apertures 111 of the lower housing element 106 are somewhat elongated in the vertical direction (i.e., in a direction normal to the plane of the

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housing element 106). This feature has the practical effect of making the upper and lower housing elements 104, 106 conform more readily to the shape of the patient's finger 112 when the latter is received within the probe 100. Specifically, the elongated pin apertures allow the portion of the patient's finger 112 inserted into the open end 154 of the probe (FIG. 3) to act as a fulcrum for a "separating" force generated by the biasing springs 133 such that the common ends 109 of the upper and lower housing elements 104, 106 are forced apart by, inter alia, the bias spring separating force. This separating force is generated by the offset 160 of the bias spring ends 145a, and connecting section 145b from the axis 123 of the spring, as shown in FIG. 3. When the user grasps the recesses 150 of the housing elements 104, 106 and squeezes, the pins 125 are forced to the fully compressed position within the elongated pin apertures 111; that is, the pins are forced against the bottom edge of the elongated apertures 111 in order to allow the probe 100 to be opened. However, once the finger 112 is inserted into the probe, the disproportionate compression of the finger 112 (due to the interaction of the angled housing elements 104, 106 and the substantially cylindrical finger 112) and the aforementioned bias spring separating force, act to force the common end 109 of the probe housing elements 104, 106 apart, thereby making upper and lower housing elements 104, 106 more parallel to each other as shown in FIG. 3. This "dislocation" of the upper element 104 with respect to the lower element 106 allows more of the surface area of the upper and lower support surface elements 114, 116 (described below) to contact the finger 112, and for more even pressure distribution thereon.

As previously discussed, the housing elements 104, 106 are adapted to receive first (upper) and second (lower) support surface elements 114, 116, respectively, which provide support and alignment for the tissue material, such as the finger 112 shown in FIG. 3, when the probe 100 is clamped thereon. When assembled as in FIGS. 2a and 3, the housing elements 104, 106 and support surface elements 114, 116 form interior cavities 115a, 115b within the upper and lower housing elements 104, 106, respectively, which contain, inter alia, the light source 103 and photodetector 105 as described in greater detail below. The upper support surface element 114 is fashioned from a substantially pliable polymer such as silicone rubber, so as to permit some deformation of the element 114 when in contact with the fairly rigid upper portion 113 of the patient's finger 112. In one embodiment, the upper element 114 is constructed as a membrane of polymer. The lower surface element 116 is fashioned from a substantially solid and rigid (i.e., higher durometer) polymer. This harder, solid polymer is used for the lower surface element 116 since the lower portion of the finger 112 is generally more fleshy and deformable, thereby allowing the skin and tissue material thereof to deform and contour to the shape of the inner region 122 of the lower surface element.

The upper and lower surface elements 114, 116 also include first and second apertures 117, 119, respectively, which communicate with the patient's tissue material when the finger 112 is inserted in the probe 100. The apertures allow for light energy to be transmitted between the light source 103 and tissue material, and similarly between the tissue material and detector 105. The first aperture 117 is also axially located with the second aperture 119 in the vertical dimension, such that when the probe 100 is in the closed configuration with the patient's finger 112 disposed between the upper and lower surface support elements 114, 116, light emitted by the light source 103 through the first

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aperture 117 is transmitted through the finger 112 and the second aperture 119 and received by the detector 105. Hence, the light source 103, first aperture 117, second aperture 119, and detector 105 are substantially axial in this configuration.

The lower support element 116 is further provided with a positioning element 196 disposed near the pivot element 108 and common end 109 of the probe 100, as shown in FIGS. 2 and 3. The positioning element 196 is oriented vertically with respect to the lower support element 116 so as to stop the distal end of the patient's finger from being inserted into the probe past a certain point, thereby facilitating proper alignment of the finger 112 within the probe 100, especially with respect to the source and detector apertures 117, 119. While the present embodiment uses a semi-circular tab as the positioning element 196, it will be recognized that other configurations and locations of the element 196 may be used. For example, the tab could be bifurcated with a portion being located on the upper support surface element 114, and a portion on the lower support surface element 116. Alternatively, the positioning element could be in the form of a tapered collar which receives, aligns, and restrains only the distal portion of the patient's finger. Many such alternative embodiments of the positioning element are possible, and considered to be within the scope of the present invention.

As further described below, the lower surface element 116 optionally includes a chamber 126 coincident with the second aperture 119 to assist in mitigating the effects of patient movement during light transmission or reflection. The structure of such chambers is described in detail in U.S. Pat. No. 5,638,818, entitled "Low Noise Optical Probe", which is incorporated herein by reference. In general, the chamber 126 acts to isolate a portion of the tissue material directly over the chamber 126 and aperture 119, thereby reducing compression of that tissue during movement. This tends to stabilize the signal generated by the detector 105, since the optical transmission path through the tissue material is effectively stabilized and constant. The chamber 126 is deep enough that the detector 105 and the bottom of the chamber 126 do not come into contact with the easily compressible portion of the tissue material, even when the tissue material is caused to move. The movement of venous blood due to compression is also minimized in the field of view of the detector 105.

In the embodiment of FIGS. 2-4, the light source 103 is comprised of one or more devices such as semi-conductive light emitting diodes (LEDs), although it will be appreciated that other light generating devices may be used. The light source 103 may be chosen to emit light at a single known discrete wavelength, at multiple discrete wavelengths, or across a portion of the spectrum (such as that emitted by a "white light" LED), depending on the needs of the particular application. In the present embodiment, the light source 103 consists of two diodes emitting light energy in the infrared and red regions of the electromagnetic spectrum, and a parallel resistor (or resistors) used for security. The construction and operation of such light source drive circuitry is described in U.S. Pat. No. 5,758,644 incorporated herein by reference.

As shown in FIG. 2, the light source 103 is affixed in a recess 170 formed in the interior portion of the upper support surface element 114, and aligned with the aperture 117 formed within the upper support surface element 114. An adhesive such as a UV-cured silicone-based gel is used to affix the LED 103 to the recess 170, although other adhesives or attachment schemes may be employed. The light

energy detector **105**, in the present case a semi-conductive photodetector, is received within a corresponding recess **172** within the lower support surface element **116**. As with the LED **103**, the photodetector **105** may be fixed within its recess **172** according to a number of different methods, including but not limited to adhesive, a press fit, or clear epoxy resin which transmits light over a range of wavelengths of interest.

As illustrated in FIG. 2, the upper support surface element **114** further includes an optical energy shield **130** which, in the present embodiment, is comprised of a plurality of shield tabs **132a**, **132b**, **132c** which protrude from the upper support surface element **114**. The shield **130** and tabs **132a**, **132b**, **132c** are sized and shaped so as to conform substantially to the outer circumference of the patient's finger **112**, providing at least a partial seal against ambient light incident on the probe exterior and otherwise exposed portions of the finger **112**. Since the shield **130** is also formed from the same pliable polymer as the first support surface element **114**, both the shield and upper support surface element are capable of automatically adapting their shape substantially to that of the patient's finger **112** without further adjustment. Specifically, as the probe **100** is closed around the finger **112**, the central region of the pliable upper support surface element **114** engages the more rigid upper portion of the patient's finger, thereby compressing the element **114** in this region. This tends to draw the proximal portions **190a**, **190b** of the shield tabs **132a**, **132b**, **132c** toward the finger **112**, thereby forming a better seal. In this fashion, patients having fingers of different circumferences can be accommodated with the same probe shield **130**.

As shown in FIGS. 2 and 3, the present embodiment of the optical probe **100** includes optional optically transparent covers **198a**, **198b** which are fitted at least partly within the apertures **117**, **119** formed in the upper and lower support surface elements **114**, **116**, respectively. The covers **198a**, **198b** are fabricated from a rigid or semi-rigid transparent polymer (such as polycarbonate), although other materials may be substituted. The two covers **198a**, **198b** act as protection for the source **103** and detector **105** disposed thereunder, respectively. Specifically, the covers **198** are bonded to the interior surface of the upper and lower support surface elements **114**, **116** such that the outer surfaces **199a**, **199b** of the covers **198** are essentially flush with the outer surfaces of their respective support surface elements **114**, **116**. The outer surfaces **199a**, **199b** (FIG. 3) of the covers **198a**, **198b** may also be curved or contoured if desired. It is further noted that while the present embodiment utilizes covers **198** which are optically transparent, the physical and optical properties of the covers may be adjusted to produce the desired characteristics. For example, one or both of the covers **198a**, **198b** may include a scattering medium as described further below.

In an alternative embodiment, the windows for the emitter and detector are filled with a UV-cured silicone that is transparent to the wavelengths of the emitter, and the transparent covers described above are not used.

In addition to the aforementioned features, the upper and lower support surface elements **114**, **116** and light shield **130** are advantageously formed from or coated with a light absorbing material which further mitigates the effects of ambient light, as well as stray (i.e., "secondary") reflected light within the probe generated by the light source **103**. Specifically, light generated by the light source **103** can take several paths in reaching the detector, only one of which is the desired path via the aforementioned first and second apertures **117**, **119** and through the interposed tissue mate-

rial. Preferably, in order to obtain more accurate measurement of transmitted light intensity, these other paths are eliminated or attenuated. Hence, in one embodiment, the light absorbing material is disposed on the entire upper and lower surface elements **114**, **116** and shield **130** so as to substantially absorb any secondary reflections prior to being received by the detector **105**. In the embodiment of FIGS. 2-4, the upper surface element **114** (and integral shield **130**) and lower surface element **116** may be formed from a black, opaque material which both inhibits the transmission of light energy through its thickness and absorbs at least a portion of the incident light incident onto its surface. In this fashion, the absorbing material mitigates the effects of both reflections transmitted from the light source **103**, and ambient light incident on the surface elements **114**, **116**. It will also be appreciated that while the present embodiment employs surface elements **114**, **116** which are formed from an opaque material, absorptive coatings or coverings may be used as well. For example, all or a portion of the upper and lower surface elements **114**, **116** and shield **130** could be coated with a light-absorbing paint or other absorbing substance as an alternative to or in addition to the use of the aforementioned opaque material. In one embodiment, the elements **114** and **116** are white or reflective in the vicinity immediately surrounding the apertures **117**, **119**.

For example, FIGS. 2b and 2c depict one embodiment of the upper and lower elements **114**, **116**, showing nonreflective surfaces **140a** and **140b** with shading. In this embodiment, the area directly around the apertures for the LED and photodetector remain white or reflective to promote light transmission in the area of the photodetector.

In addition to the light shield and absorptive materials described above, the present embodiment utilizes an electromagnetic noise shield **185** as illustrated in FIG. 5. The noise shield **185** operates on Faraday principles to block or attenuate electromagnetic interference (EMI). The noise shield **185** has a grating **187** which permits light to pass while still blocking electromagnetic energy. In a preferred embodiment, this is a very fine screen with a large open percentage to permit as much light as possible yet still block EMI. In the illustrated embodiment, the detector shield **185** is an etched copper shield made of copper foil approximately 4 mils thick, which is wrapped around the detector **105** in a box-like fashion so as to substantially enclose the detector, significantly insulating it from an external EMI. The screen or grating **187** is etched through the shield to allow light from the light source **103** to transmit through the shield **185** to the detector **105**. The noise shield **185** is also electrically grounded to the detector ground, thereby precluding the buildup of electrical charge.

In the optical probe of FIGS. 2-4, the apertures **117**, **119** optionally may be filled wholly, or in part, by a scattering medium **180**. The scattering of the light energy within a scattering medium has been found to increase the signal-to-noise ratio of the signal generated by the detector. Ideally, the scattering medium **180** scatters but does not significantly absorb light energy at the wavelengths of significance for the operation of the probe. In other words, the material is substantially transparent to optical absorption, but none-the-less effectively scatters light energy. In general, the scattering medium **180** may comprise one of a number of fixotropic substances (i.e., substances having two or more mixed materials which are conducive to scattering). The construction and use of scattering media are further described in the aforementioned U.S. Pat. No. 5,638,818.

FIGS. 6 and 6a illustrate a second embodiment of the optical probe of the present invention. As illustrated, this

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second embodiment of the probe **200** comprises, inter alia, first and second housing elements **204**, **206**, upper and lower support surface elements **214**, **216**, and pivot assembly **208** as previously described. The embodiment of FIG. **6** further includes a plurality of discrete, removable shield tabs **220** which are mounted to the optical probe **200** using a sliding key and channel arrangement. Specifically, each of the tab elements **220** are formed such that the edge **222** which engages the optical probe **200** is shaped or keyed so as to fit within the channels **224** located on the outer portions of and running longitudinally along the upper housing element **104** of the optical probe, as shown in FIG. **6a**. The present embodiment employs channels **224** and edges **222** which are substantially square in cross-section, although it will be recognized that other cross-sectional shapes including rectangles, polygons, and triangles and circles may be used with equal success. The use of a square (or other shape) for the edges **222** and their corresponding channels **224** prevents significant lateral movement or rotation of the edges **222** in the channels **224** when installed. As shown in FIG. **6a**, the channels **224** may be further formed such that a pair of support ridges **225a**, **225b** act to support the tabs **220** when the latter are inserted into the channels **224**, thereby adding additional rigidity to the shield tabs **220**. The shield tabs **220** may also be made interchangeable from side to side if desired.

The shield tabs **220** of the embodiment of FIGS. **6** and **6a** are fabricated from a somewhat rigid yet flexible polymer such as silicone rubber of durometer 45A. This construction permits their removal from and insertion into the channels **224** of the housing element **204**, while allowing some degree of flexibility so as to adapt to the shape and size of each individual patient's finger when the probe is fitted on the patient.

It will be appreciated that while the shield tabs **220** of the present embodiment are mounted using channels disposed along the outer portions of the upper housing element **204**, other locations and mounting configurations may be used. For example, the channels **224** could alternatively be located in the lower housing element **206**, with the shield tabs **220** extending upward when inserted rather than downward as in FIG. **5**. Similarly, the channels **224** could be located within the upper or lower support surface elements **214**, **216**. Furthermore, retaining mechanisms other than the aforementioned channels **224** may be used, such as pins and corresponding holes, adhesives, or other devices well known in the mechanical arts. In yet another alternative embodiment, the shield tabs **220** could be part of a single component which is received within the channels **224** or other retaining mechanism on the optical probe. A great variety of optical shield configurations according to the present invention are possible, all of which achieve the goals of minimizing noise within the probe **200** while allowing removability of the shield.

As illustrated in FIG. **7**, another embodiment of the optical probe of the present invention is described. In this embodiment, the probe **300** includes a light energy source **303** and detector **305**, upper and lower housing elements **304**, **306**, upper and lower support surface elements **314**, **316**, and pivot element **308**, as in the prior embodiment. However, the embodiment of FIG. **7** utilizes the principle of optical reflectance rather than optical transmission; hence, the light source **303** and detector **305** are both co-located within the upper housing element **304**, in direct proximity to one another. Source and detector apertures **317**, **319** are formed within the upper support surface element **314**, their axes being canted at a predetermined angle **320** relative to

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the normal direction **321** and along a common plane **323**. This arrangement permits light to impinge on the surface of the patient's finger **112**, be reflected therefrom, and received by the detector **305** via the detector aperture **319**.

It will be recognized that while the source **303** and detector **305** and their respective apertures **317**, **319** are located generally in the upper housing element **304** and upper support member **314**, they may equally as well be located in the lower housing element **306** and support member **316** if desired. Many of such alternative orientations are possible.

Additionally, although the embodiment of FIG. **7** has the axis of the apertures **317**, **319** canted at a predetermined angle, such angle is not necessary for the operation of the optical probe. For example, the apertures **317**, **319** could alternatively be closely co-located in a vertical orientation; light scattered from various portions of the tissue material of the patient's finger **112** beneath the source aperture **317** would be reflected into the detector aperture **319** and received by the detector **305**.

FIG. **8** illustrates one embodiment of the probe monitoring circuit of the present invention provided with a sensor and a monitor. In this embodiment, the monitoring circuit is comprised generally of a counter **406**, non-volatile storage device **420**, and monitoring LED **426**. Circuitry useful for driving the light source and processing the detector signals is known in the art. The monitoring circuit counts the number of LED activations which is obtained from the modulated drive signals. For example, in one embodiment, the modulated drive pulses to at least one LEDs are also communicated to the counter **406**. Specifically, the light source LEDs **103a**, **103b** are pulsed (modulated) to alternatively emit red and infrared light energy, respectively, as controlled by the LED driver **424** and the microprocessor **418**. The drive signals to at least one of the LEDs also clocks the counter **406**. In one preferred embodiment, the counter only increments once for a predefined number of activations. In other words, a divide by X circuit forms a portion of the counter. This is because the number of cycles is very high, and a divide circuit reduces the capacity requirements of the counter. The construction and operation of electronic counters are well known in the electrical arts, and accordingly will not be described further. Advantageously, the counter is maintained in a non-volatile RAM (NVRAM) which maintains a running count. When a predetermined number is reached, an LED **426** is activated. This number is determined by, for example, empirical data relating to the longevity of the probe to a given number of detector pulses. The monitoring LED **426** is mounted in the probe housing **102** or remotely from the probe if desired (such as on the probe control module, not shown), and is readily visible to the operator.

It will be recognized that the aforementioned probe monitoring function can be accomplished using a number of different circuit configurations well known in the art. For example, in one alternative embodiment, circuitry is employed which measures the actual time the detector **105** generates an output signal. In another embodiment, the number of pulses applied to each of the LEDs **103a**, **103b** in the light source **103** is counted. Many other such alternative embodiments are possible.

It will be further recognized that while the circuit of FIG. **8** utilizes an LED **426** for indicating probe age, other indicating devices such as incandescent bulbs, liquid crystal displays (LCDs), or even audio generators may be used.

The pulsed emissions from the LEDs are also detected by the detector **105**. The detected signals are amplified by the

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amplifier 402. The amplified signals are then filtered using a band-pass or other filter 404, thereby passing only that portion of the detected signals corresponding to the desired band of light intensity.

The probe of the present invention may be employed in any circumstance where a measurement of transmitted or reflected energy is to be made, including but not limited to measurements taken on a finger, an earlobe, a lip, or a forehead. Thus, there are numerous other embodiments which will be obvious to one skilled in the art, including but not limited to changes in the shape of the probe and its components, changes in the materials out of which the probe is made, and changes in the shape, dimensions, and location and orientation of the apertures and shield. Furthermore, the probe of the present invention may be employed in measurements of energy or radiation other than light energy as defined herein. Depending upon the type of energy which is most advantageously utilized in a measurement, the type of transmitter or receiver of energy may be changed. The invention may be embodied in other specific forms without departing from its spirit or essential characteristics. The described embodiments are to be considered in all respects only as illustrative and not restrictive. The scope of the invention is, therefore, indicated by the appended claims rather than by the foregoing description. All changes which come within the meaning and range of equivalency of the claims are to be embraced within their scope.

What is claimed is:

1. An optical probe for obtaining data from the tissue material of a living organism, comprising:

a first housing element having a first support surface for supporting said tissue material, and a first aperture formed therein;

a second housing element having a second support surface and a second aperture formed therein, said second housing element being located proximate to said first housing element and rotatably attached thereto so as to permit said tissue material to be positioned there between;

a light energy source disposed within said first housing element, said light energy source being positioned such that at least a portion of the light energy emitted is transmitted through said first aperture;

a light energy detector disposed within said second housing element, said light energy detector being positioned so as to receive at least a portion of said light energy transmitted by said light energy source through said tissue material and said second aperture; and

a light shield mounted to at least one of said first and second housing elements and located proximate to said tissue material, said light shield attenuating at least a portion of ambient light energy incident on said tissue material,

wherein at least one of the first support surface and the second support surface includes a first area having a first attenuation property and a second area having a second attenuation property substantially different from said first attenuation property.

2. The optical probe of claim 1, wherein said first and second housing elements are rotatably attached to one another via at least one pivot assembly.

3. The optical probe of claim 2, further comprising a biasing member which biases said first and second housing elements together when said tissue material is received there between.

4. The optical probe of claim 3, wherein said biasing member comprises at least one spring.

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5. The optical probe of claim 4, wherein said at least one spring is mounted such that its longitudinal axis is coincident with an axis of said pivot assembly.

6. The optical probe of claim 1, wherein said shield comprises a plurality of shield tabs.

7. The optical probe of claim 6, wherein at least one of said plurality of shield tabs is removably attached to said optical probe.

8. The optical probe of claim 7, wherein said at least one of said plurality of shield tabs is attached to said optical probe using a key and channel arrangement.

9. The optical probe of claim 1, wherein said shield is formed within said first support surface.

10. The optical probe of claim 1, further comprising a chamber having an entrance in the form of said second aperture, wherein at least a portion of said tissue material covers said second aperture and is supported by said second support surface around said aperture, said chamber isolating at least a portion of said tissue material during optical analysis thereof.

11. The optical probe of claim 1, further comprising an optical scattering medium disposed within at least one of said apertures.

12. A method of measuring a physical property using an optical probe, comprising:

forming a housing element capable of receiving tissue material, said housing element having a first aperture and second aperture formed therein, said first and second apertures being located proximate to said tissue material;

generating light energy using a light energy source; transmitting said light energy through said first aperture onto said tissue material;

detecting, via said second aperture, at least a portion of said light energy generated by said source and transmitted onto said tissue material, using a detector;

shielding said detector through at least a partial seal from light energy not generated by said light energy source and not transmitted through said first aperture; and

absorbing in a first area of the housing element at least a portion of said light energy not generated by said light energy source or not transmitted onto said tissue material;

reflecting in a second area of the housing element different from the first area, at least a portion of said light energy transmitted onto said tissue material; and

generating a signal based on said light energy detected by said detector.

13. The method of claim 12, further comprising the act of isolating at least a portion of said tissue material using a chamber formed within said housing element in order to increase the accuracy of said signal.

14. The method of claim 13, further comprising the act of scattering at least a portion of said light energy generated by said optical source and wherein said housing element further includes an optical scattering medium disposed within at least one of said first and second apertures.

15. The method of claim 12, further comprising the act of shielding said detector from electromagnetic interference using a Faraday shield.

16. The method of claim 12, wherein the act of detecting at least a portion of said light energy generated by said source and transmitted onto said tissue material comprises the act of detecting light energy transmitted through said tissue material.

17. The method of claim 12, wherein the act of detecting at least a portion of said light energy generated by said

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source and transmitted onto said tissue material comprises the act of detecting light energy reflected from the surface of said tissue material.

18. An optical probe comprising:

- a housing capable of receiving at least a portion of the tissue material of a patient, said housing having first and second apertures formed therein, said first and second apertures being proximate to said tissue material when said tissue material is received by said housing, at least a portion of said housing comprising an absorptive material capable of absorbing at least a portion of the light energy incident thereon and at least another portion of said housing comprising a reflective material;
- a light energy source disposed within said housing, said light energy source being positioned such that at least a portion of the light energy emitted thereby is transmitted through said first aperture onto said tissue material;
- a light energy detector disposed within said housing, said light energy detector being positioned so as to receive, via said second aperture, at least a portion of said light energy transmitted onto said tissue; and
- a light shield located proximate to said tissue material and at least partially sealing said tissue material from ambient light;

wherein said light shield and said absorptive material of said housing cooperate to attenuate at least a portion of any light energy that was not generated by said light energy source or was generated by said light energy source but was not transmitted through said tissue material when said tissue material is received by said housing.

19. The optical probe of claim 18, further comprising an optical scattering medium disposed at least partly with at least one of said first and second apertures.

20. The optical probe of claim 18, further comprising an electromagnetic shield used to shield said detector from electromagnetic interference.

21. The optical probe of claim 18, wherein said absorptive material is a substantially black coating deposited on at least a portion of said housing element.

22. Data indicative of the physical condition of a patient generated using the method comprising:

- forming a housing element capable of receiving tissue material, said housing element having a first aperture and second aperture formed therein, said first and second apertures being located proximate to said tissue material;
- generating light energy using a light energy source;
- transmitting said light energy through said first aperture onto said tissue material;
- detecting, via said second aperture, at least a portion of said light energy generated by said source and transmitted onto said tissue material, using a detector;

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shielding said detector using at least a partial seal against light energy not generated by said light energy source and not transmitted through said first aperture;

absorbing in a first area of the housing element at least a portion of said light energy not generated by said light energy source or not transmitted onto said tissue material;

reflecting in a second area of the housing element different from the first area, at least a portion of said light energy transmitted onto said tissue material;

generating a signal based on said light energy detected by said detector; and

analyzing said signal in order to produce said data.

23. The data of claim 22, wherein the act of analyzing said signal comprises the act of processing at least a portion of said signal using a digital signal processor.

24. The data of claim 23, wherein the act of processing said signal comprises performing a series of mathematical operations on said signal using said digital signal processor.

25. The data of claim 24, further comprising the act of shielding said detector against electromagnetic interference using a Faraday shield.

26. The optical probe of claim 1 wherein said first attenuation property comprises absorption.

27. The optical probe of claim 1, wherein said first area is positioned to interact with the ambient light energy.

28. The optical probe of claim 1, wherein said first area is positioned to interact with the light energy which emitted from the light source and which did not transmit through the tissue material.

29. The optical probe of claim 1, wherein said first area is positioned to interact with the ambient light energy and the light energy which emitted from the light source and which did not transmit through the tissue material.

30. The optical probe of claim 1, wherein said second attenuation property comprises reflectance.

31. The optical probe of claim 1, wherein said second area is positioned to interact with the light energy which emitted from the light source and which transmitted through the tissue material.

32. The optical probe of claim 1, wherein said first attenuation property comprises absorption and said second attenuation property comprises reflectance.

33. The optical probe of claim 1, wherein said second area surrounds at least one of said first and second apertures.

34. The optical probe of claim 1, wherein the first support surface includes the first area and the second area.

35. The optical probe of claim 34, wherein the second support surface includes a third area having the first attenuation property and a fourth area having the second attenuation property.

36. The optical probe of claim 1, wherein the second support surface includes the first area and the second area.

* * * * *

EXHIBIT 21



US008781544B2

(12) **United States Patent**
Al-Ali et al.

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(45) **Date of Patent:** **Jul. 15, 2014**

(54) **MULTIPLE WAVELENGTH OPTICAL SENSOR**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 1444 days.

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(52) **U.S. Cl.**
USPC **600/323; 600/310**

(58) **Field of Classification Search**
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See application file for complete search history.

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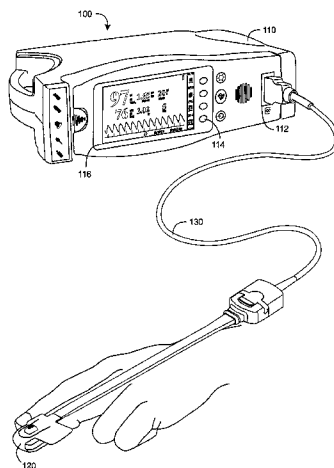
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(57) **ABSTRACT**

A multiple wavelength optical sensor has an emitter configured to radiate light having a plurality of wavelengths into a tissue site. The emitter comprises a plurality of LEDs configured in an array and connected within an electrical grid. A detector is configured to receive the light after absorption by pulsatile blood flow within the tissue site. The detector generates a sensor signal capable of being processed by a patient monitor so as to derive oxygen saturation, carboxyhemoglobin, methemoglobin and total hemoglobin.

21 Claims, 32 Drawing Sheets



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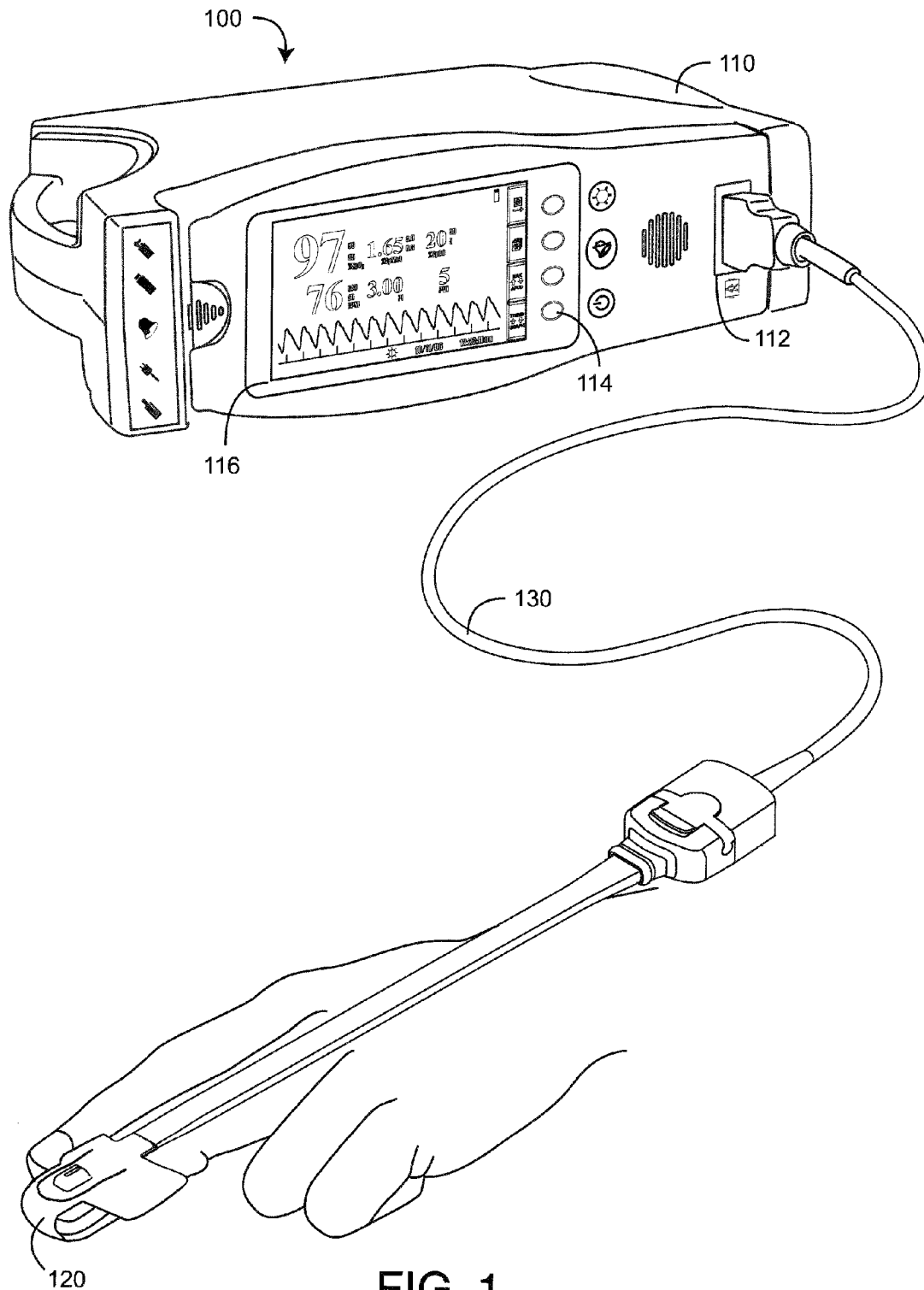


FIG. 1

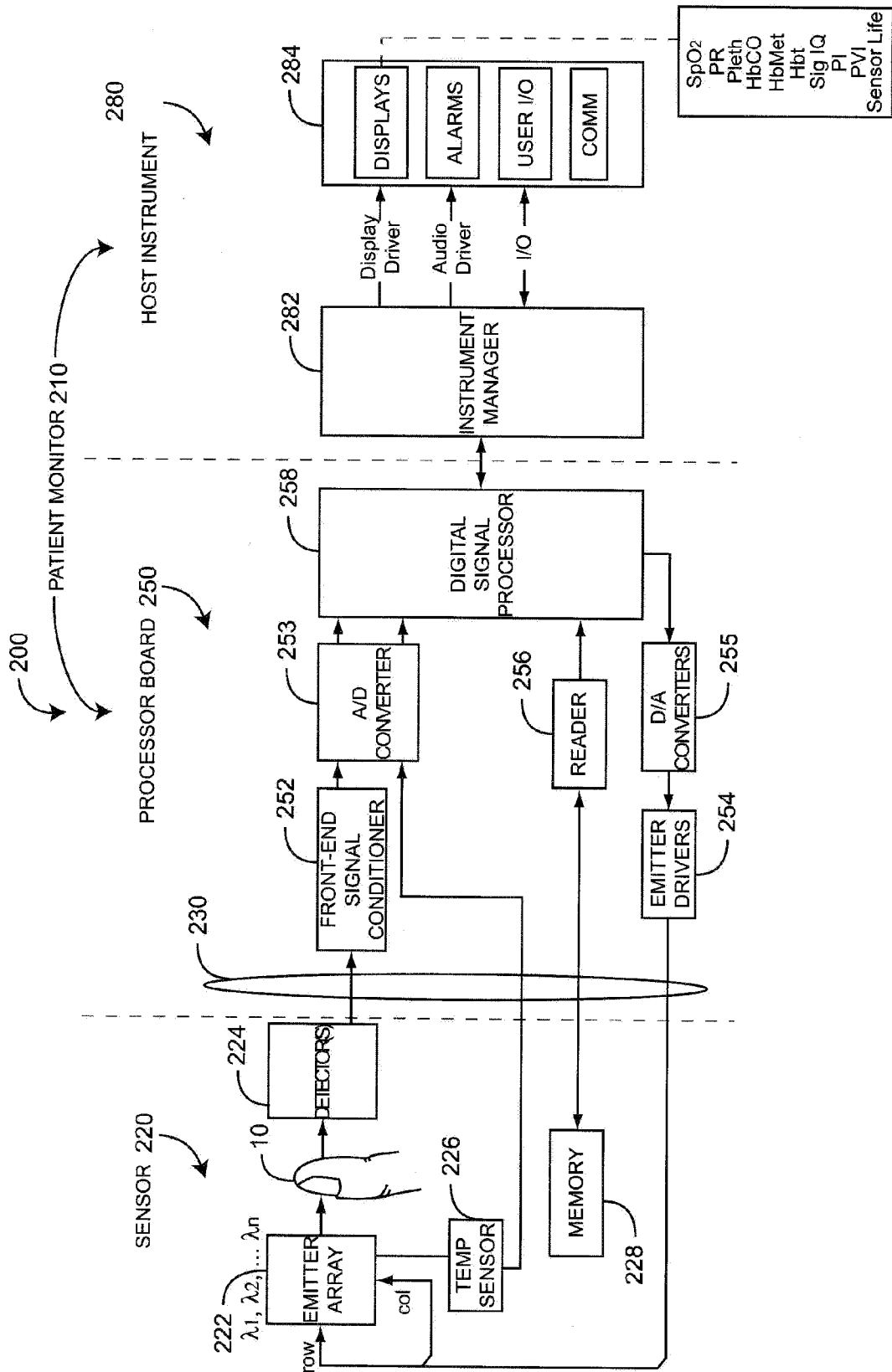


FIG. 2

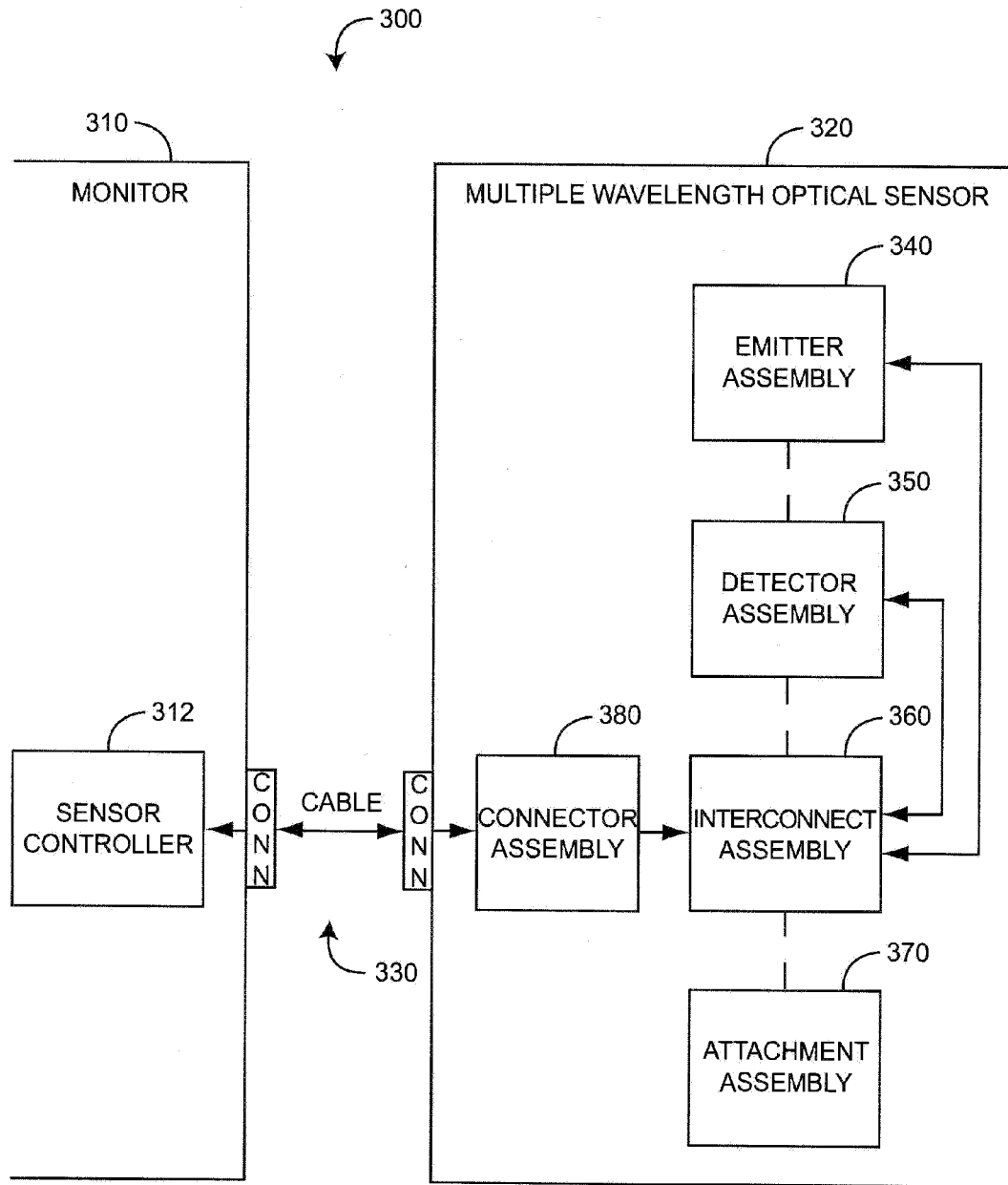


FIG. 3

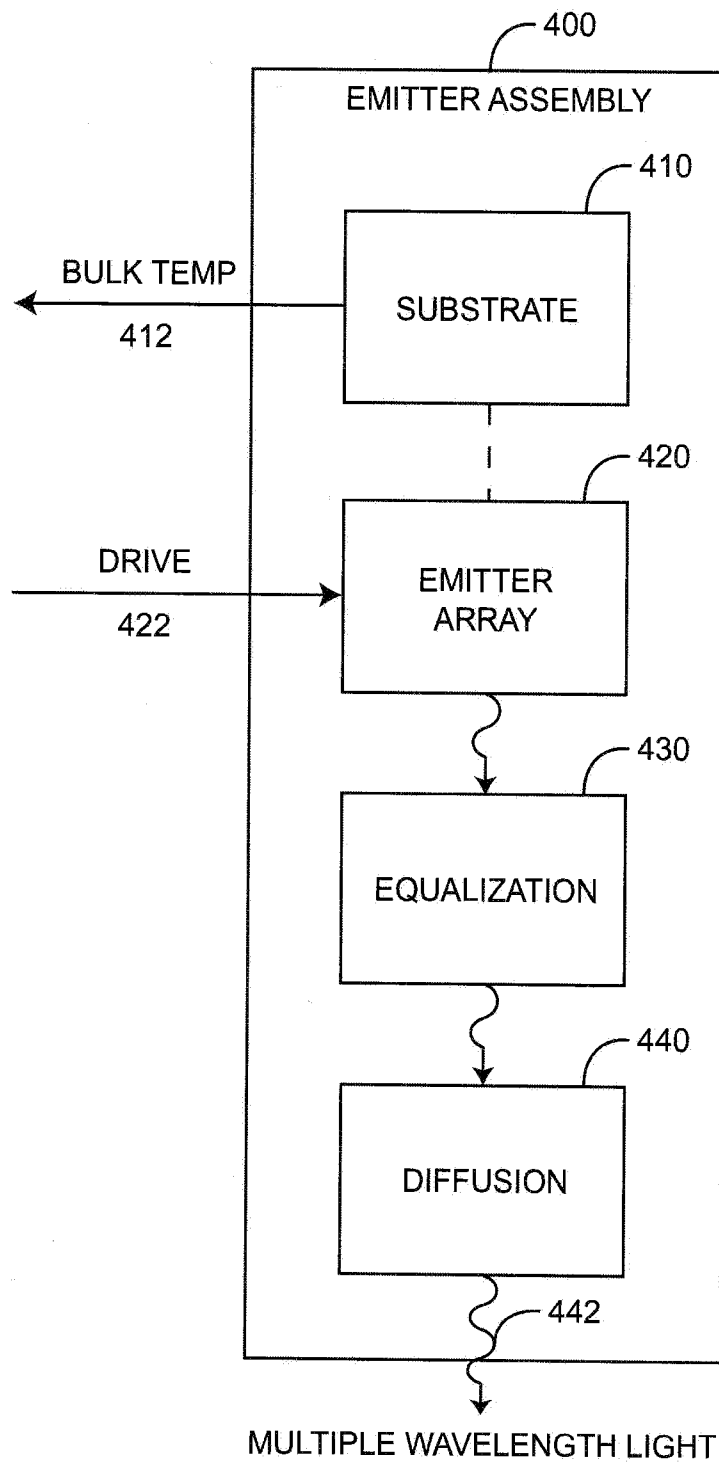


FIG. 4

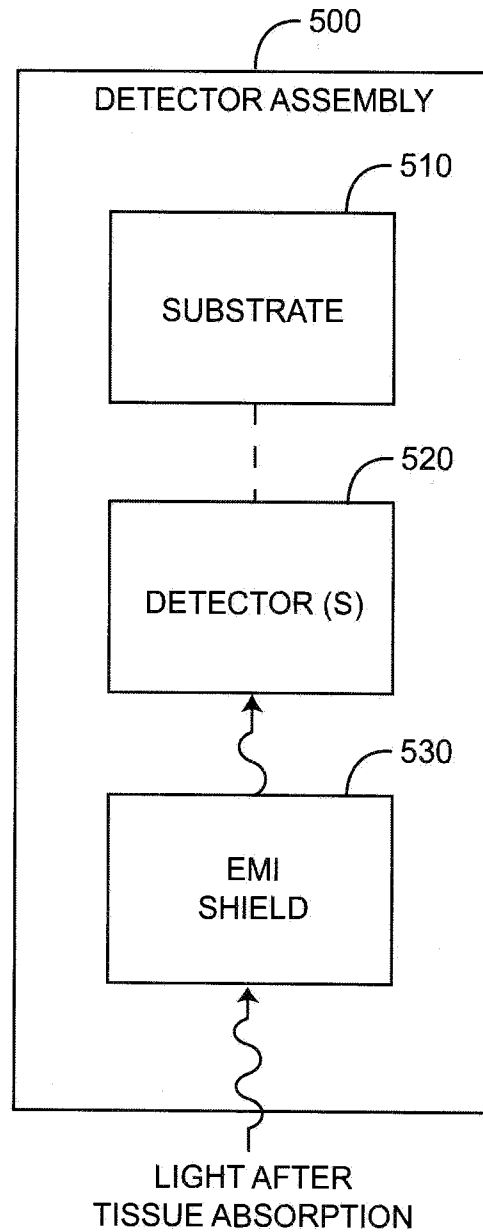


FIG. 5

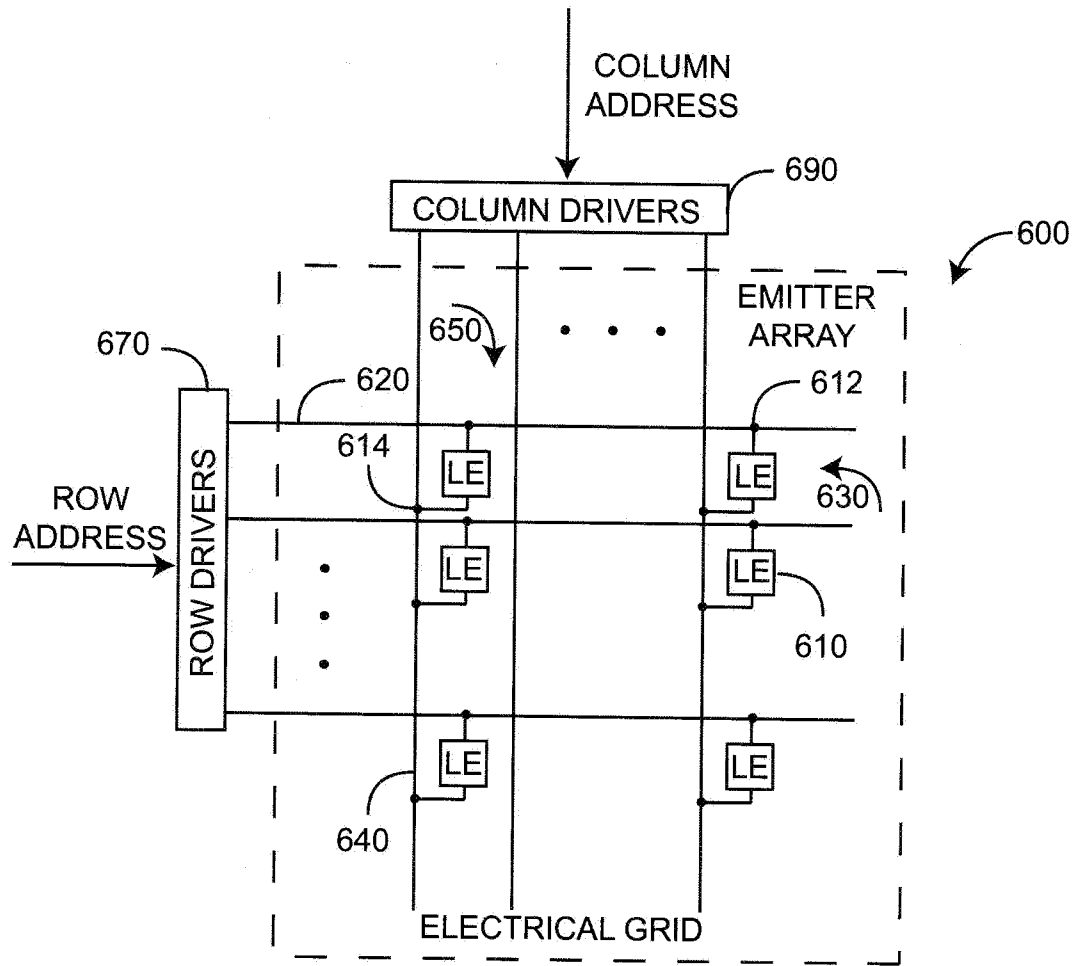


FIG. 6

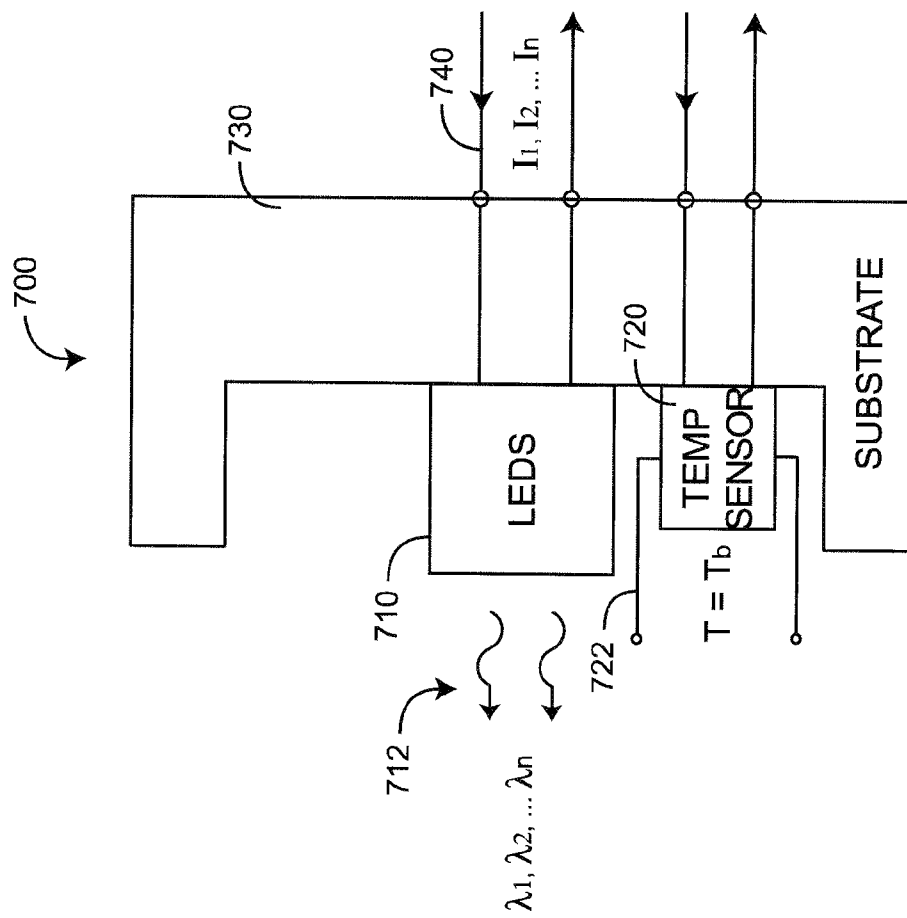


FIG. 7

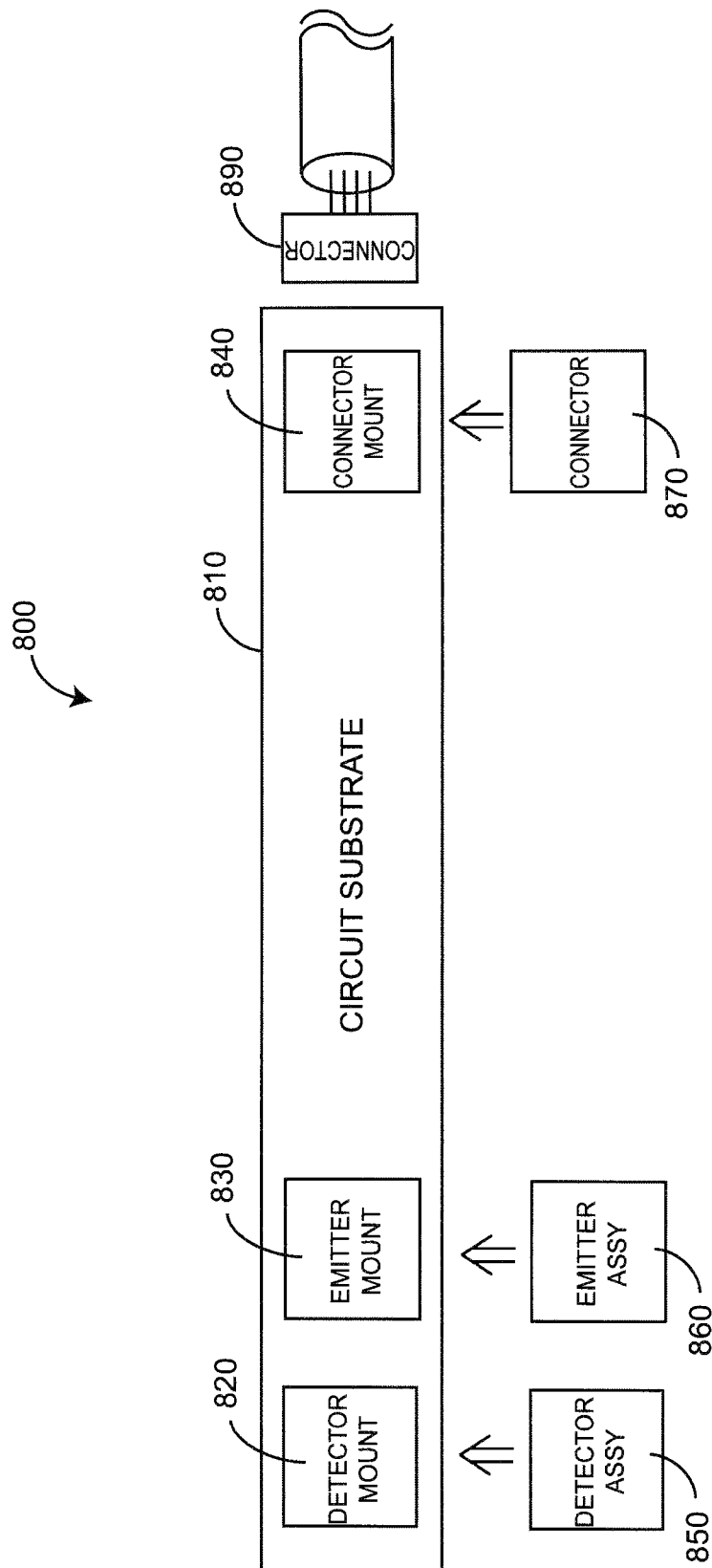


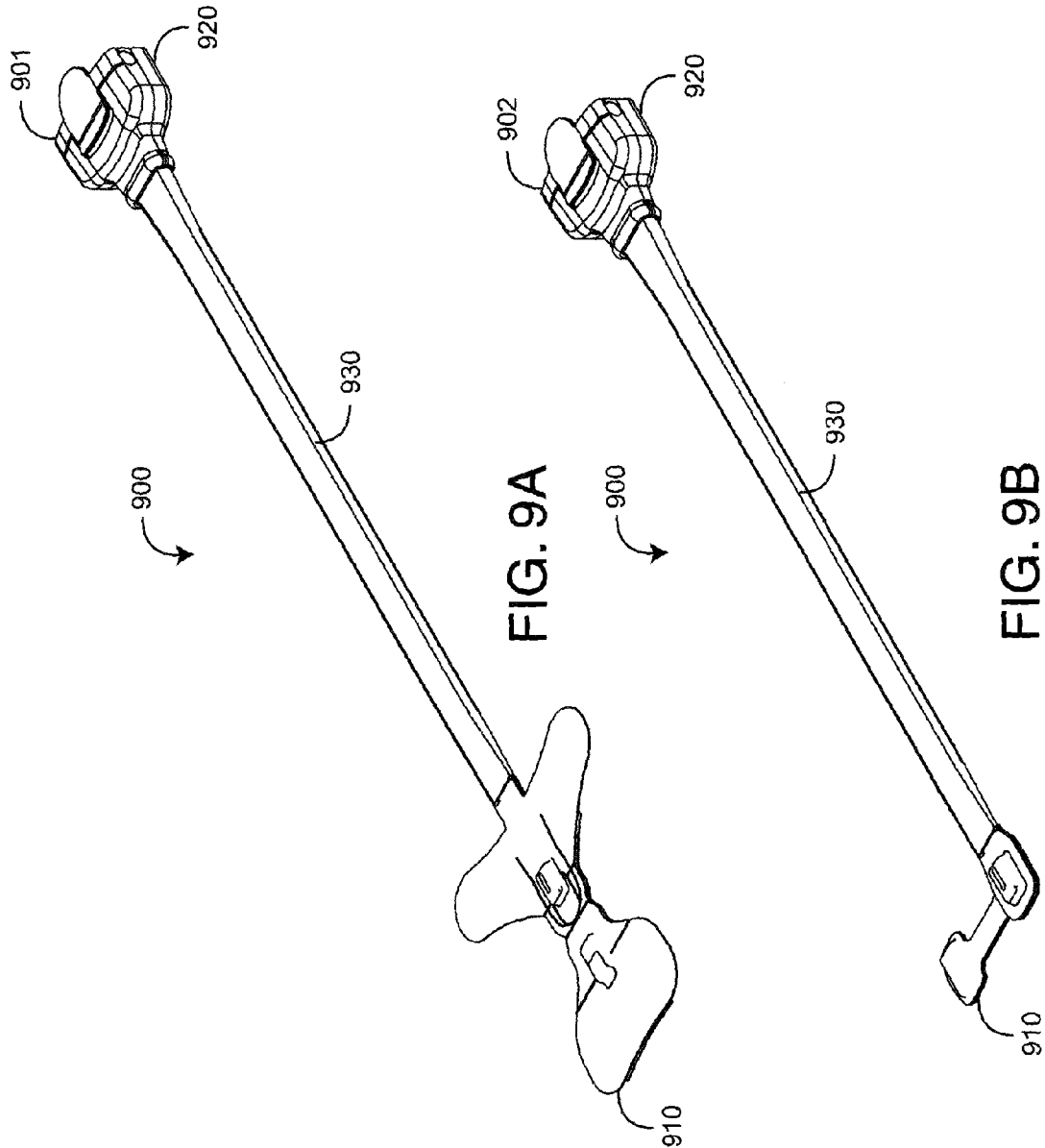
FIG. 8

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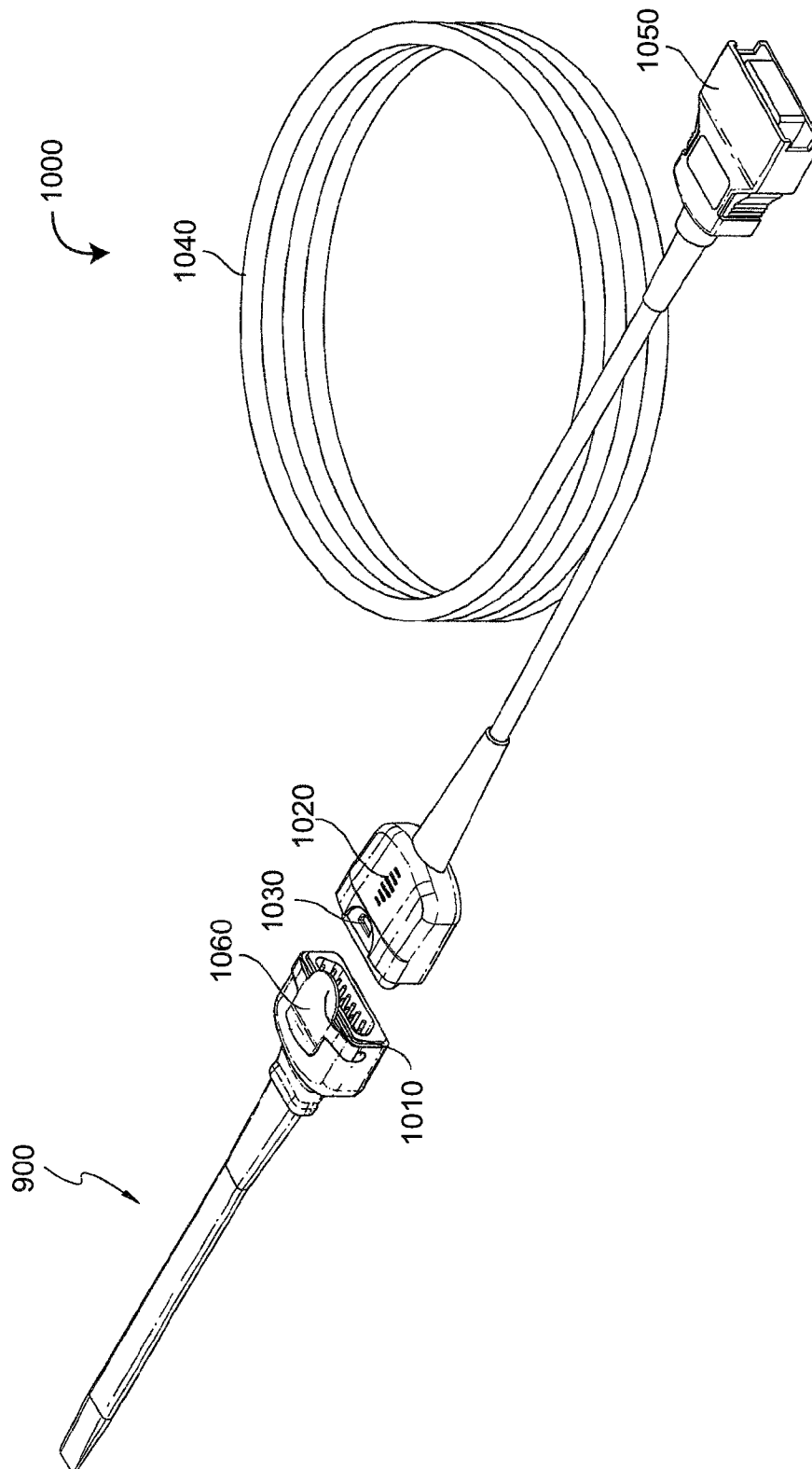


FIG. 10

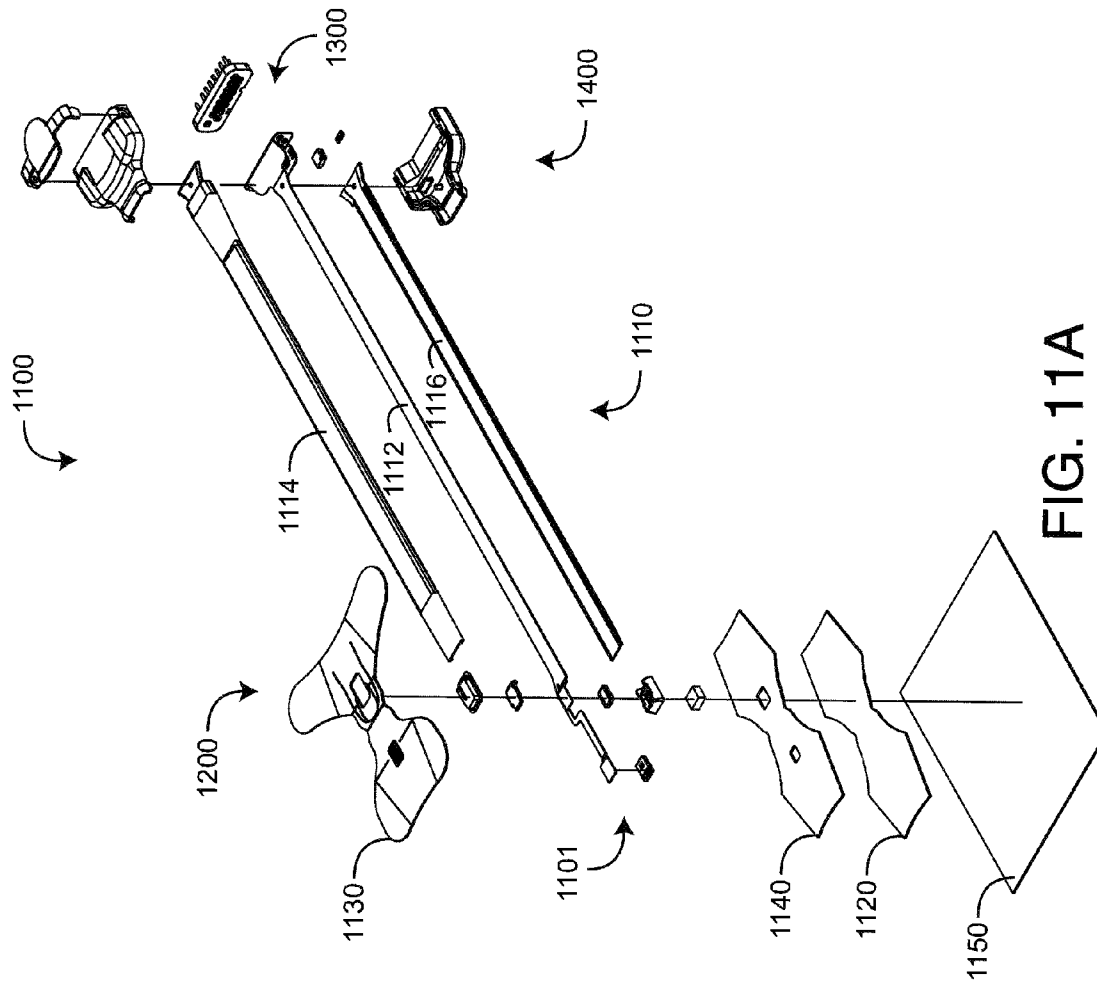


FIG. 11B

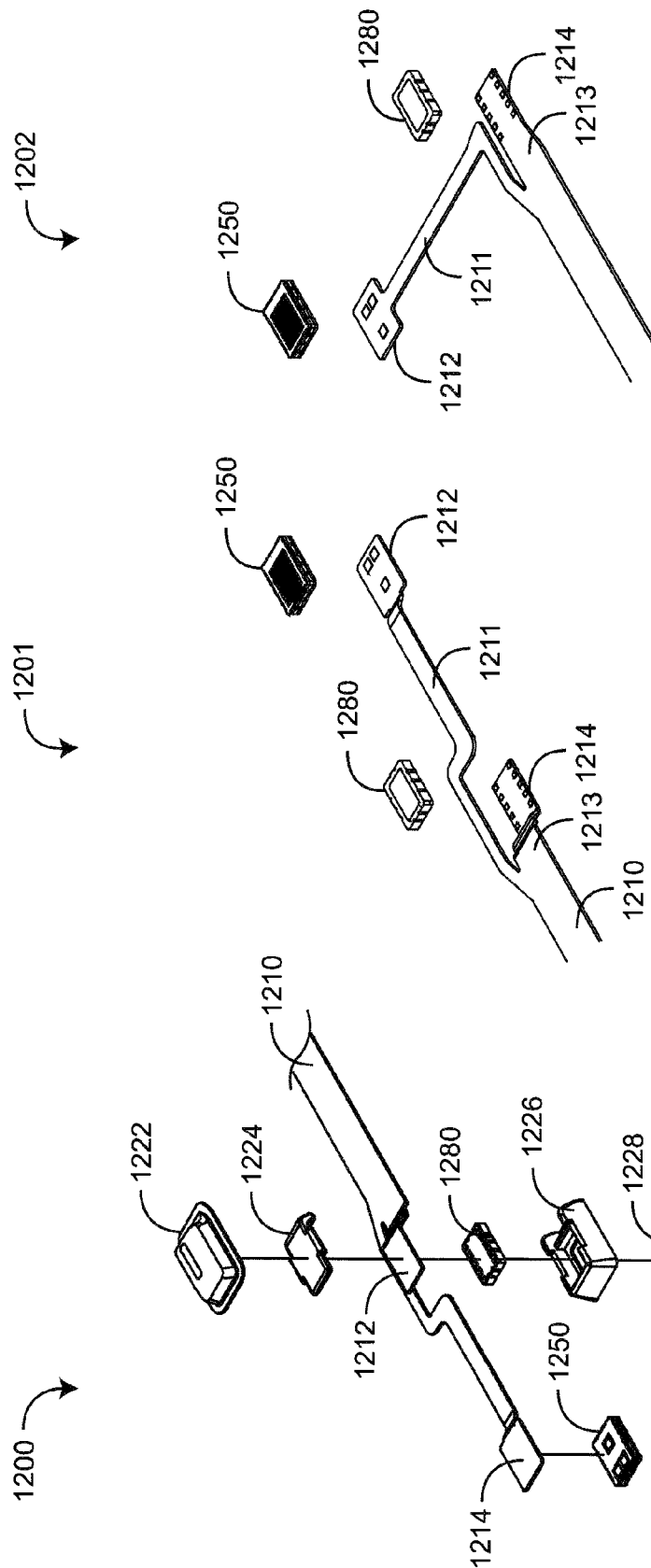


FIG. 12C

FIG. 12B

FIG. 12A

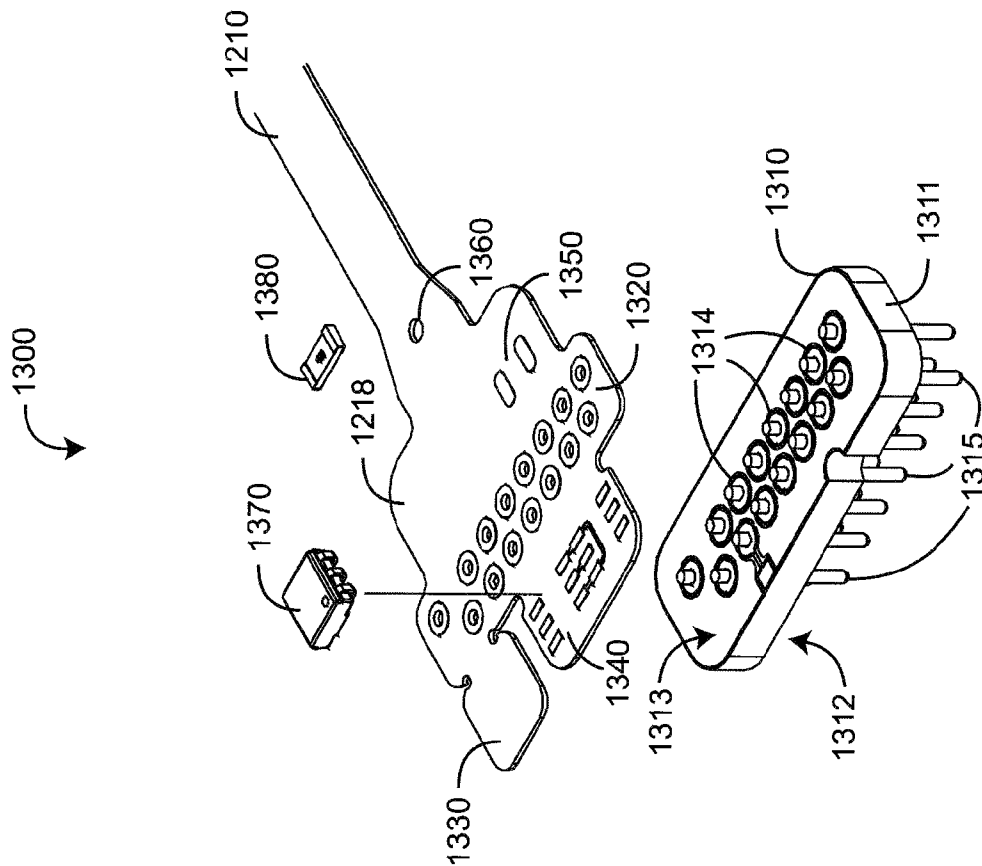
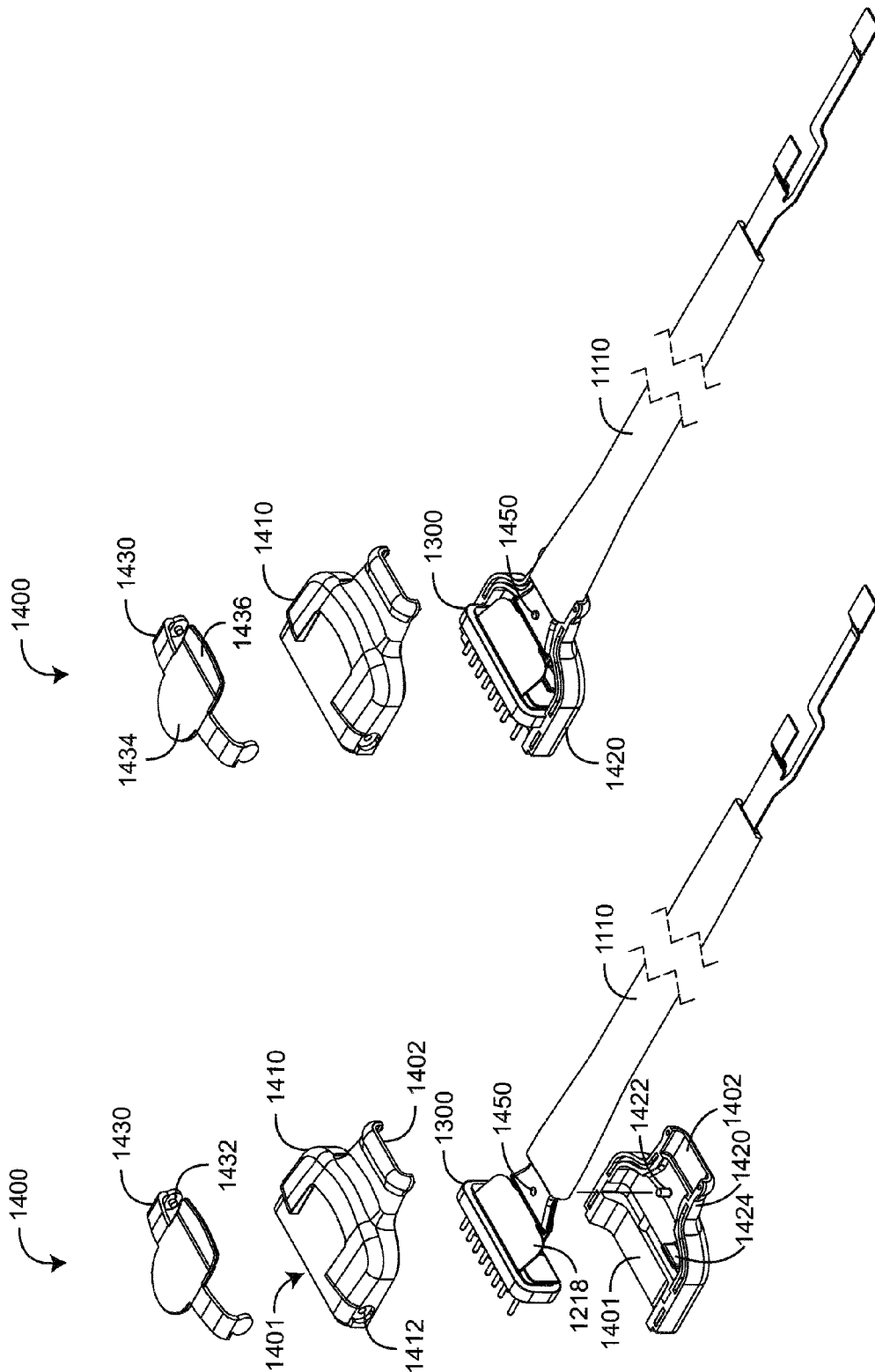


FIG. 13



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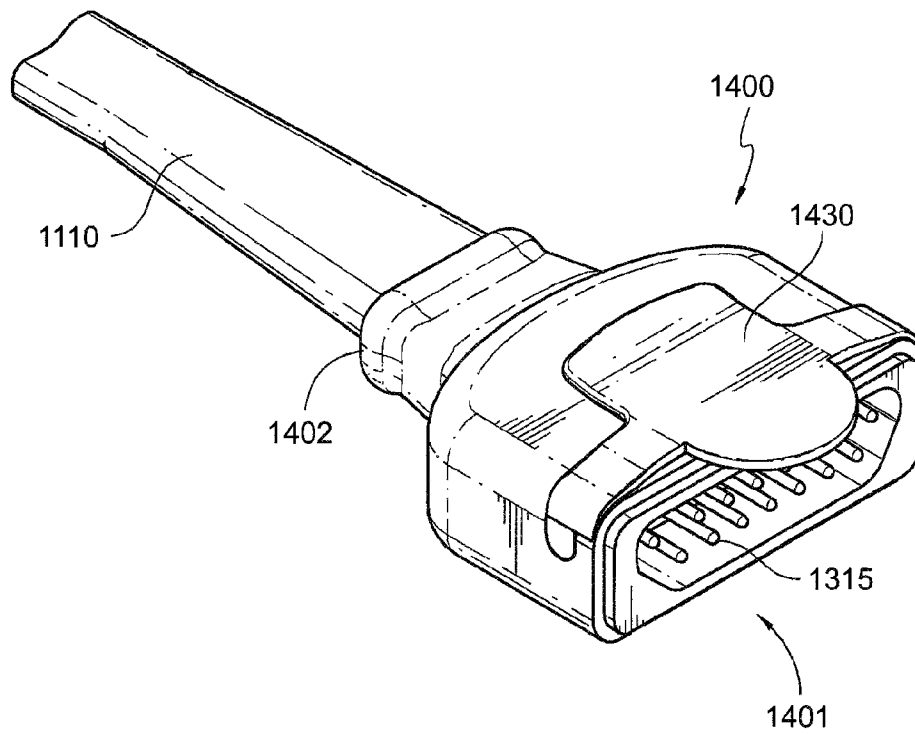


FIG. 14C

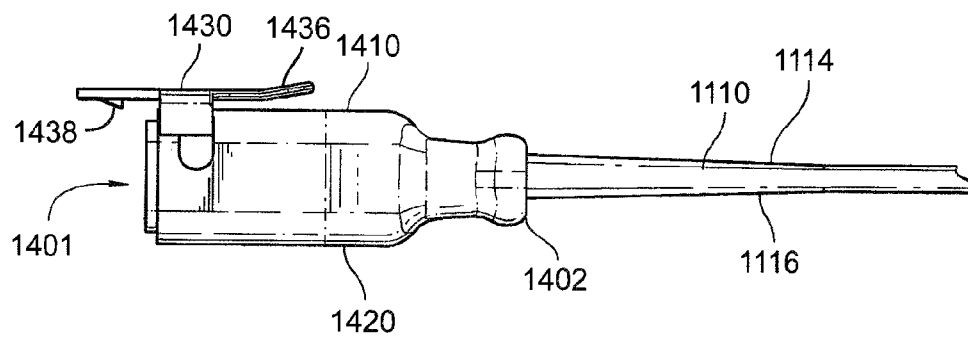


FIG. 14D

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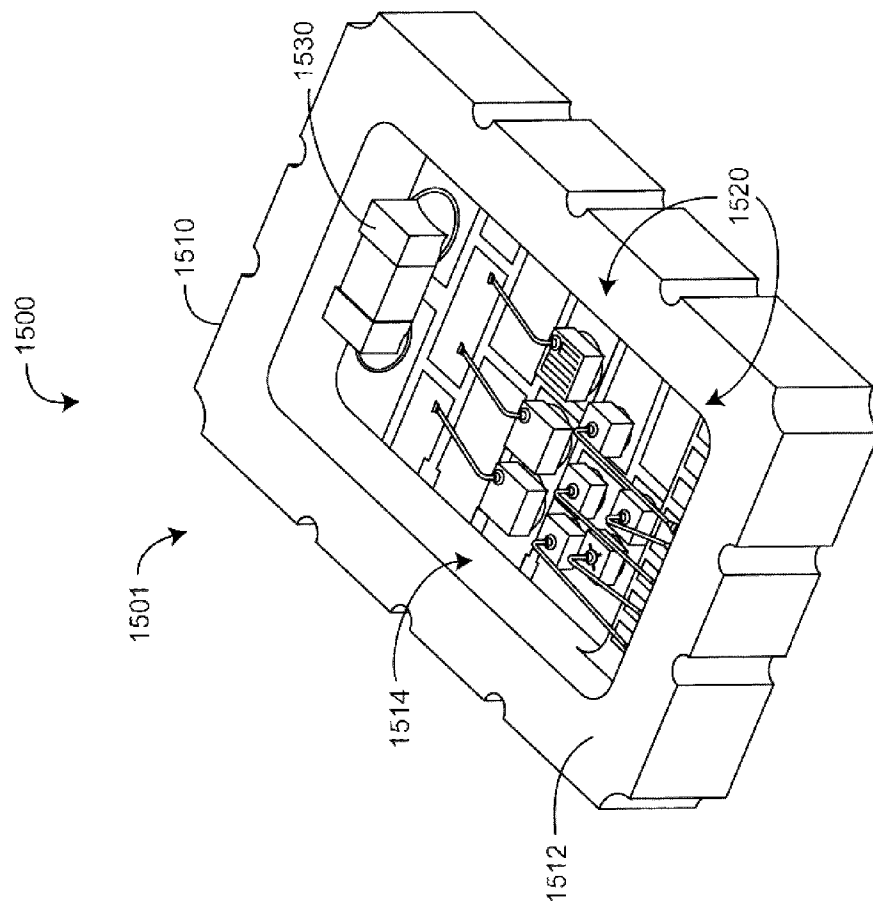


FIG. 15A

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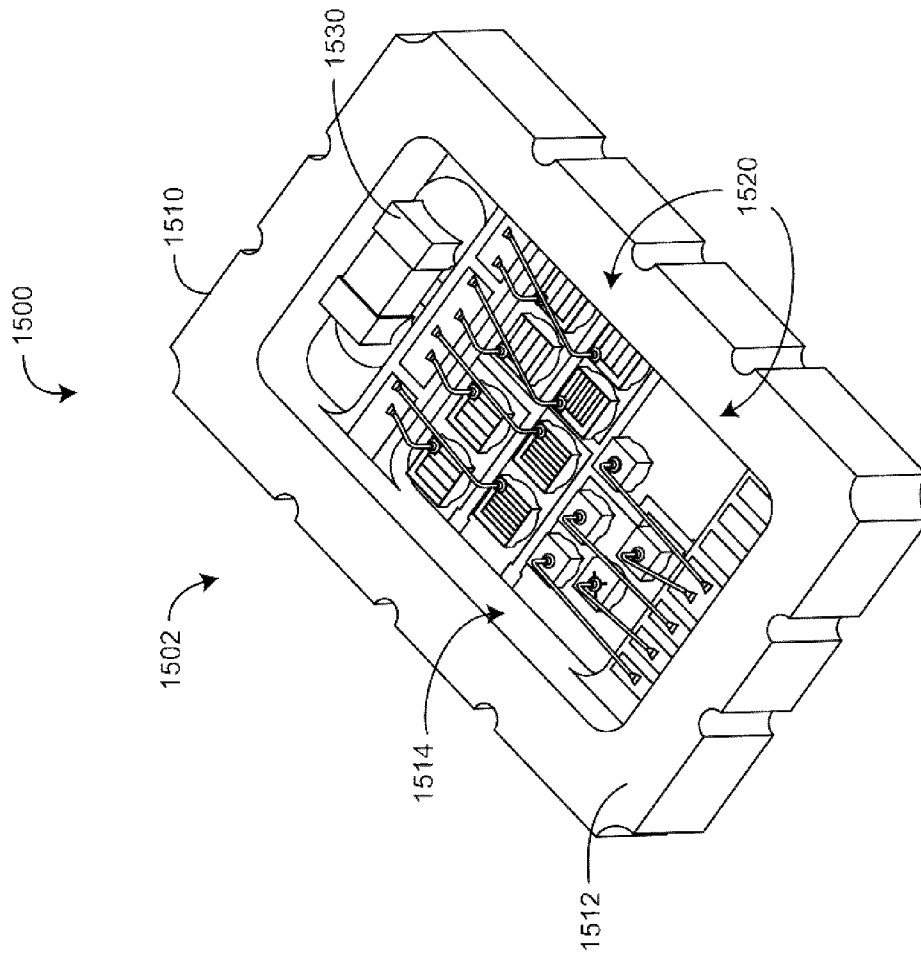


FIG. 15B

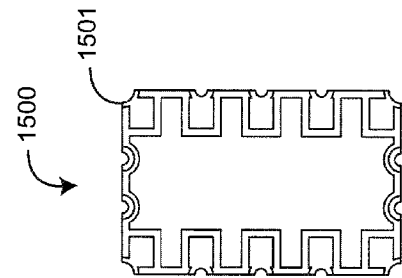


FIG. 16D

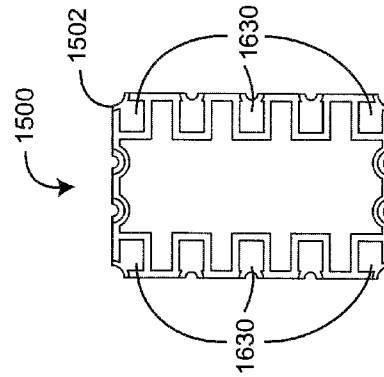


FIG. 16H

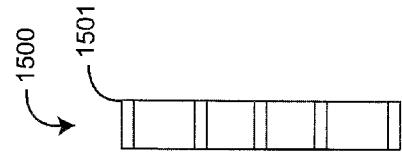


FIG. 16C

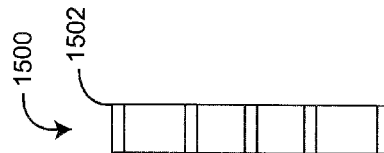


FIG. 16G

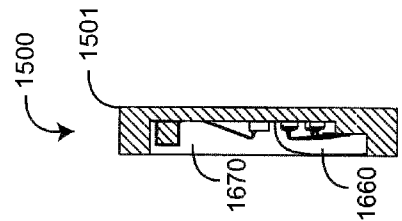


FIG. 16B

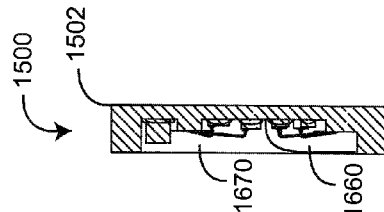


FIG. 16F

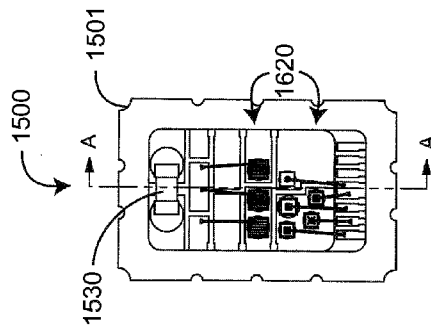


FIG. 16A

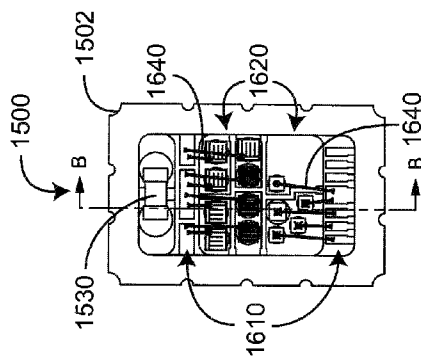


FIG. 16E

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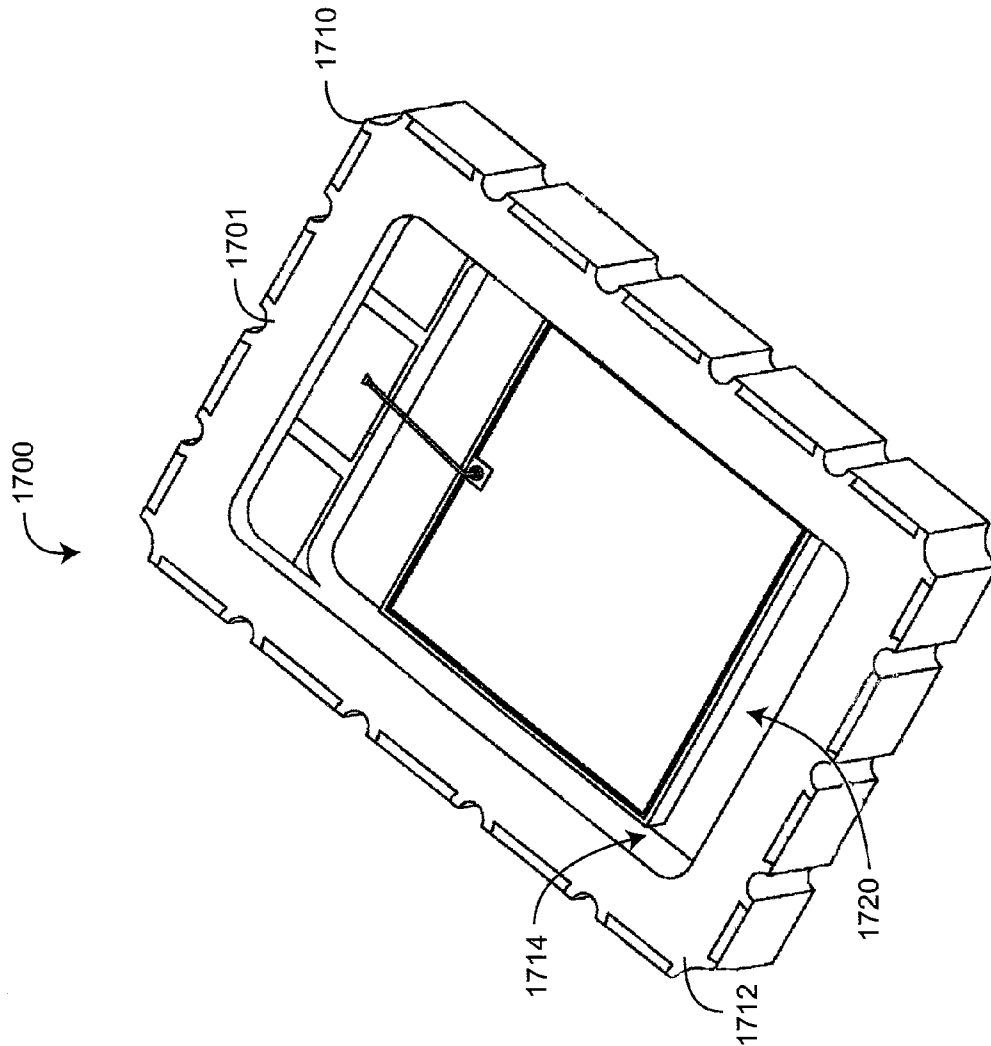


FIG. 17A

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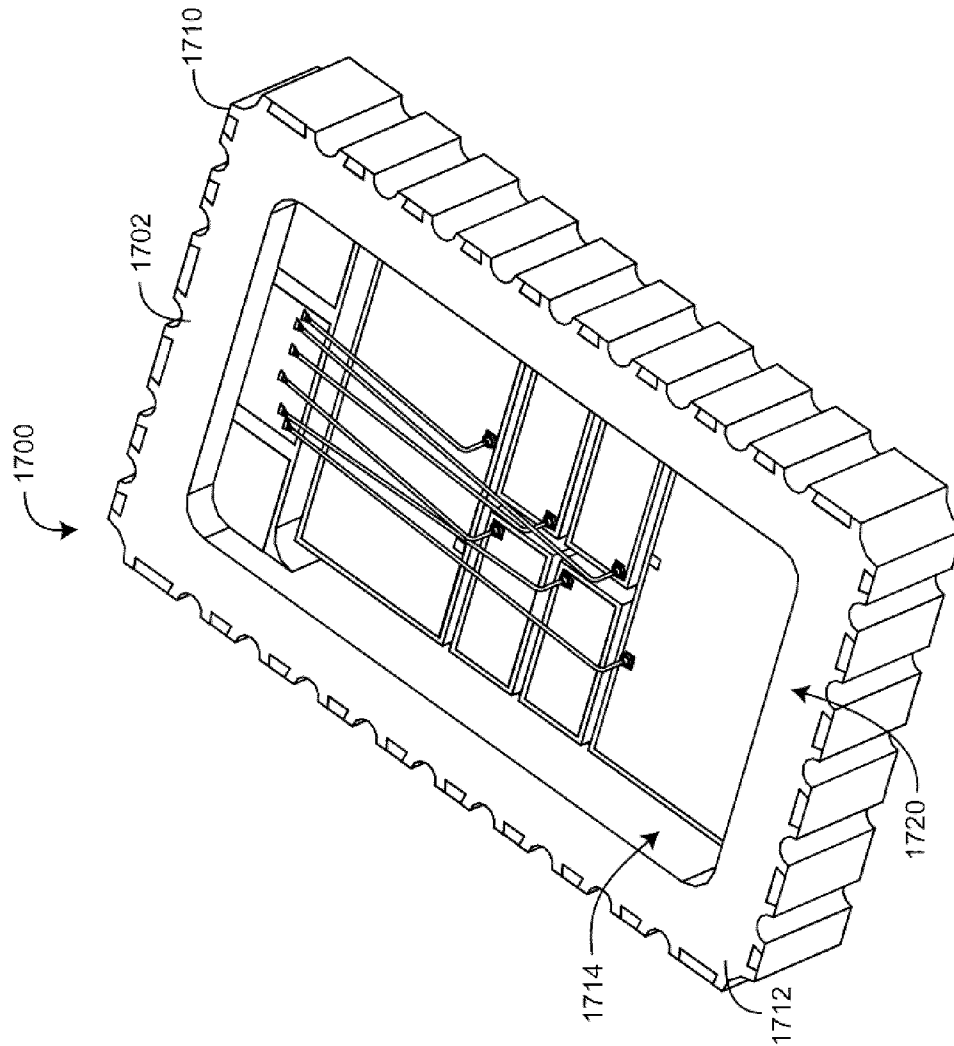


FIG. 17B

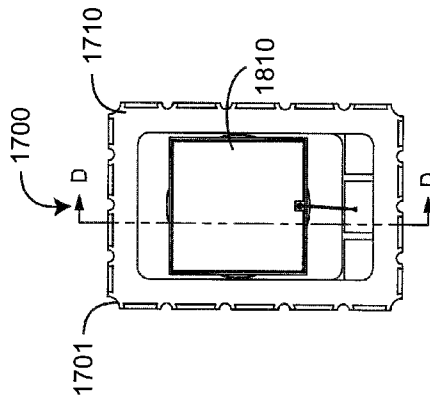


FIG. 18A

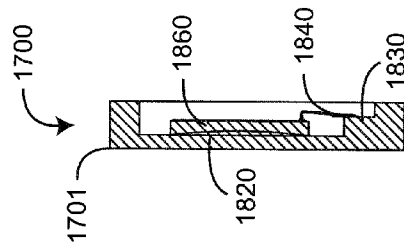


FIG. 18B

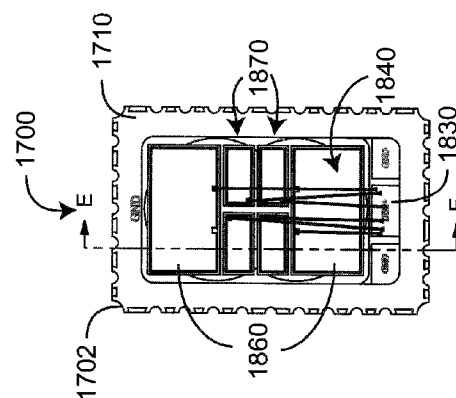


FIG. 18E

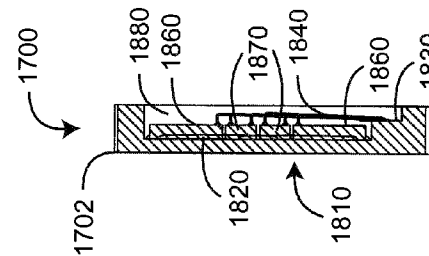


FIG. 18F

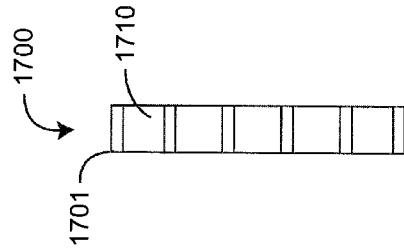


FIG. 18C

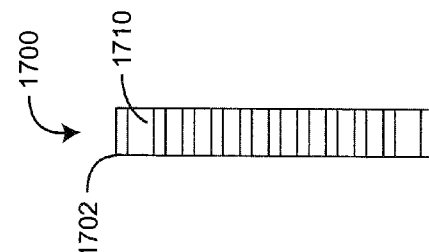


FIG. 18G

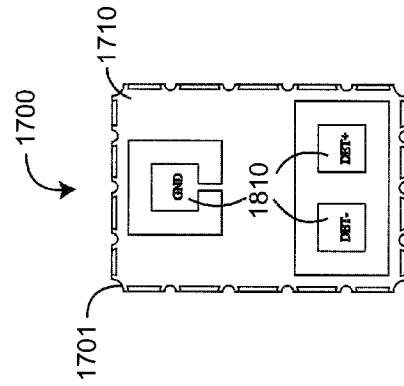


FIG. 18D

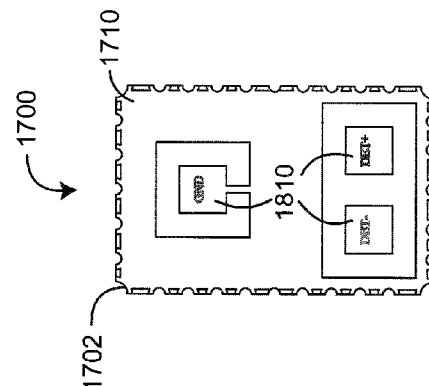


FIG. 18H

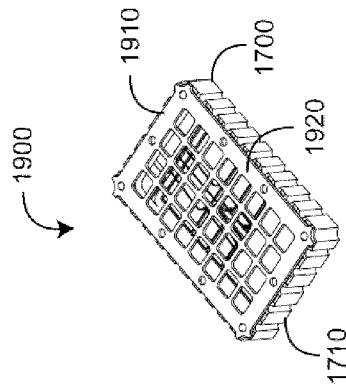


FIG. 19A

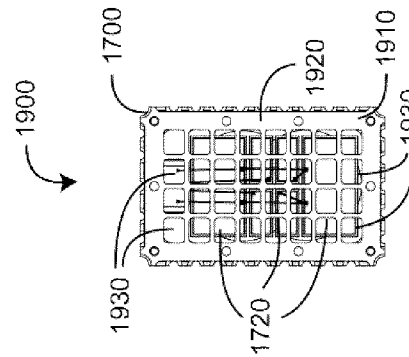


FIG. 19B

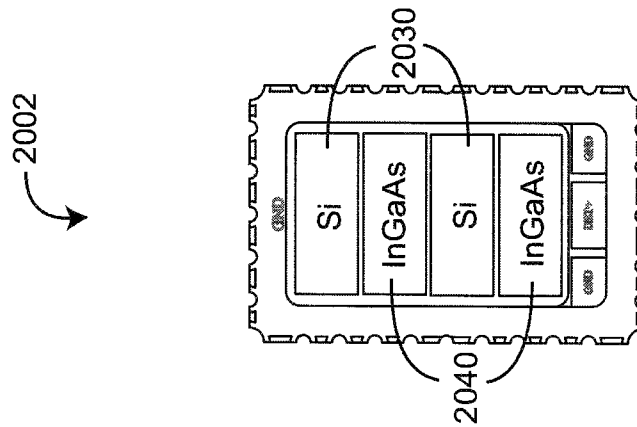


FIG. 20B

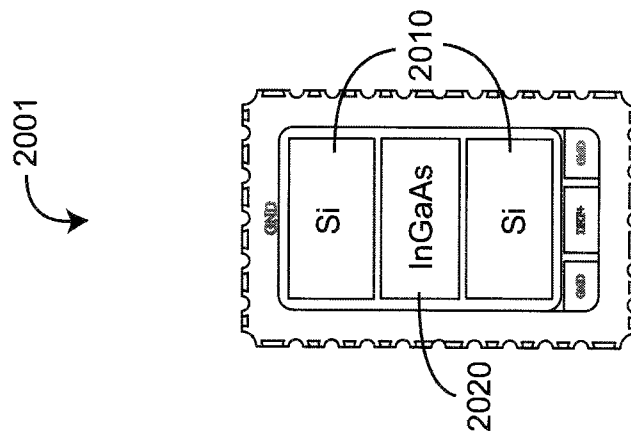


FIG. 20A

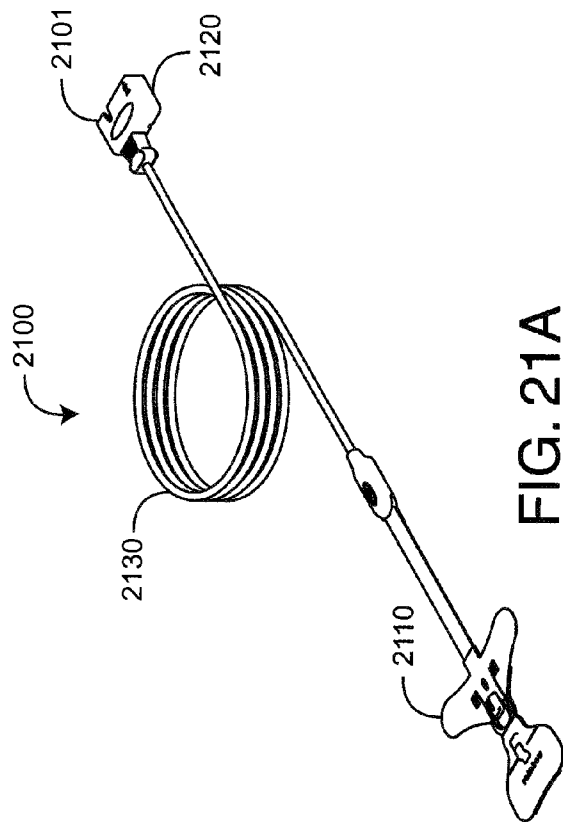


FIG. 21A

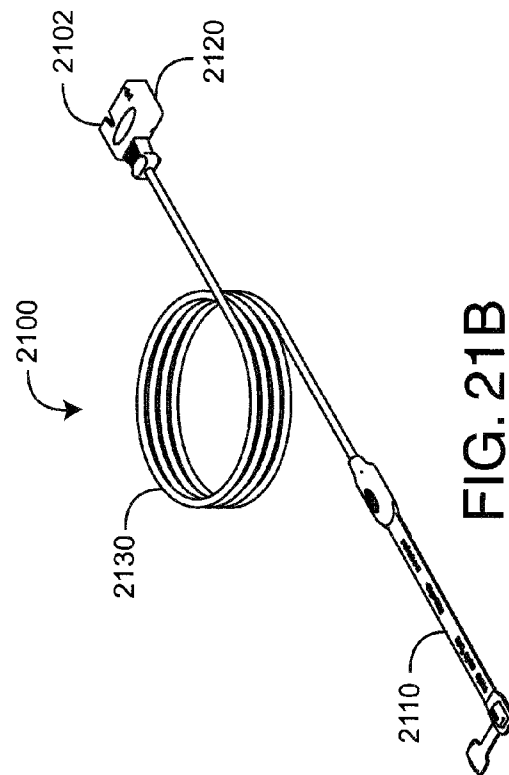


FIG. 21B

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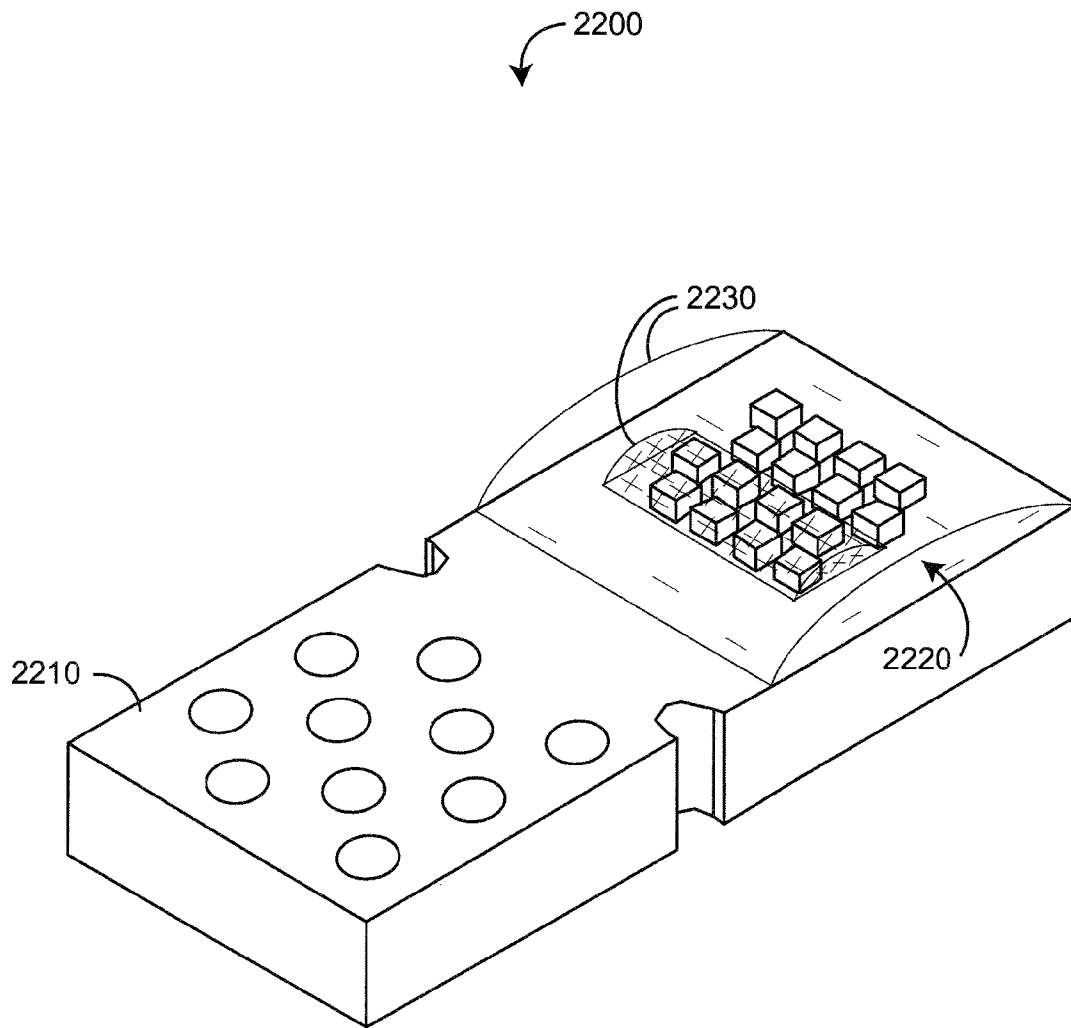


FIG. 22

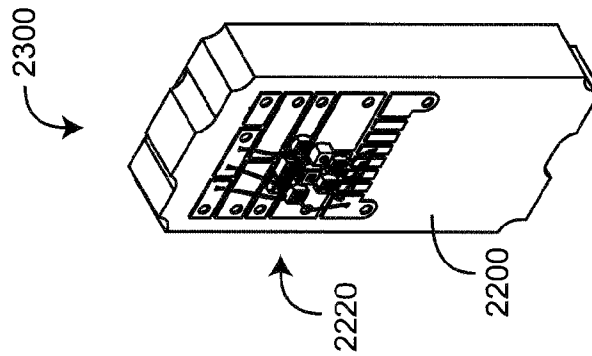


FIG. 23D

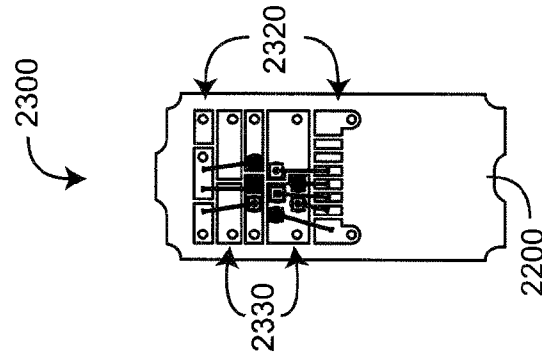


FIG. 23C

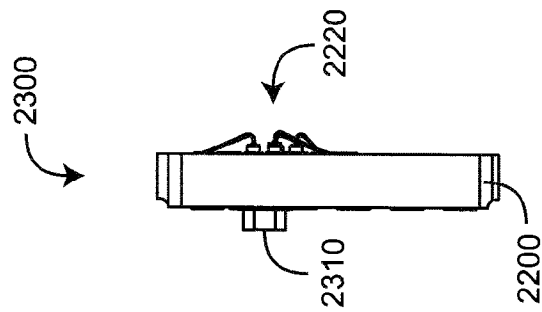


FIG. 23B

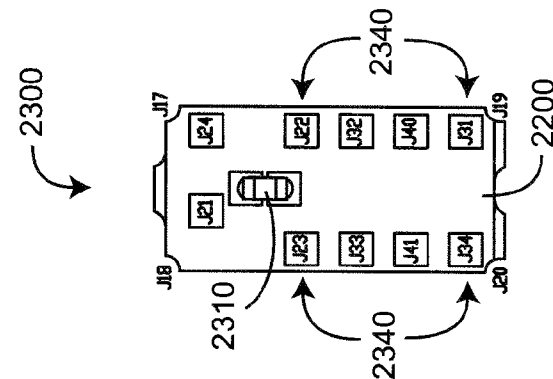


FIG. 23A

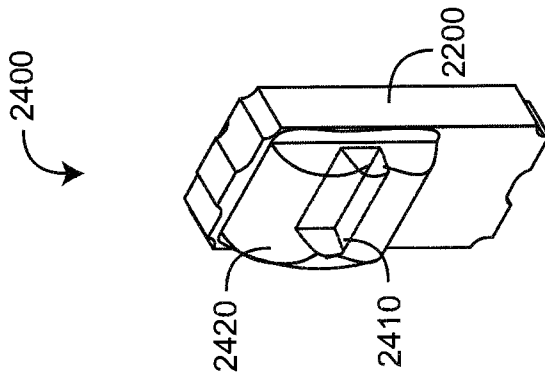


FIG. 24D

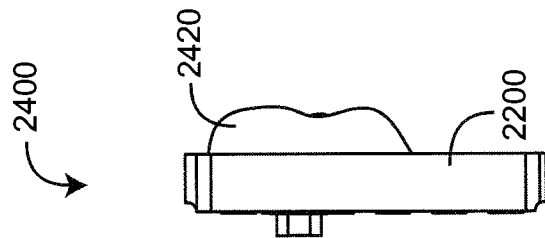


FIG. 24C

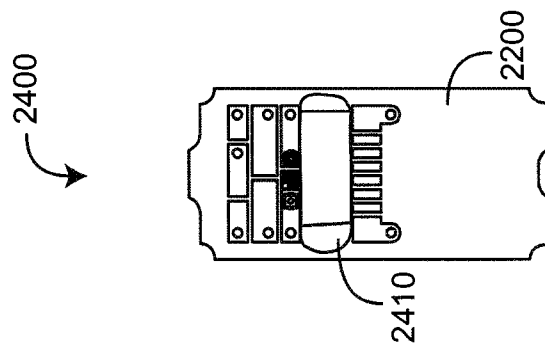


FIG. 24B

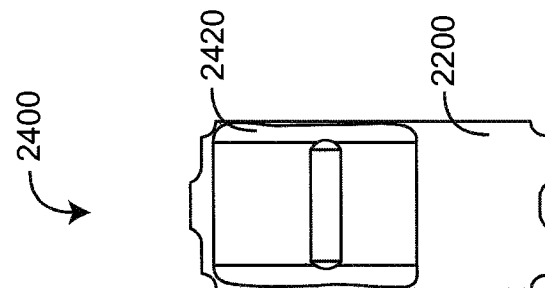


FIG. 24A

FIG. 25

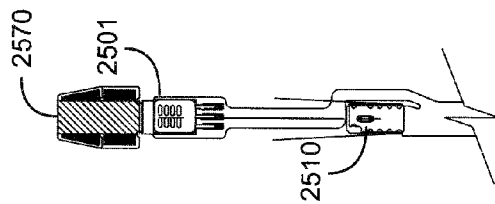


FIG. 26A

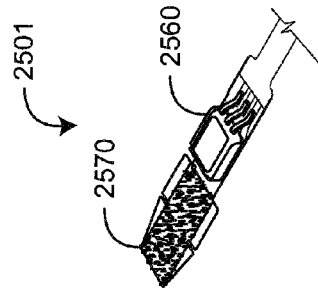


FIG. 26B

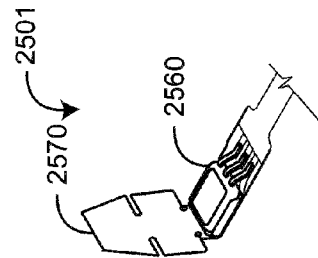


FIG. 26C

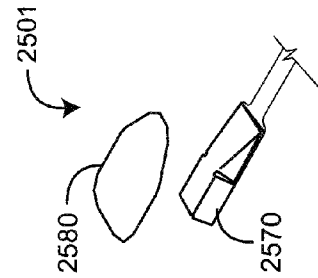


FIG. 26D

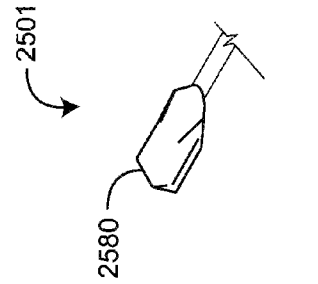


FIG. 26E

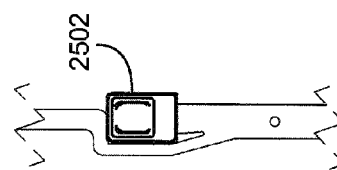


FIG. 26F

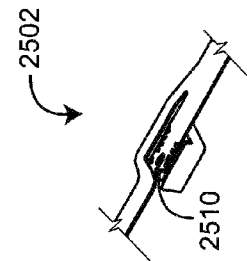


FIG. 26G

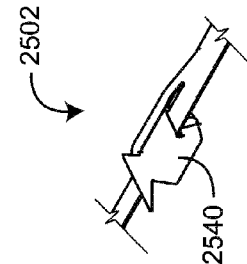


FIG. 26H

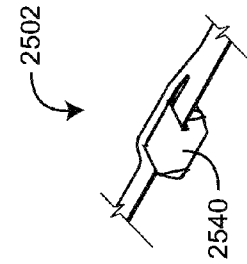


FIG. 26I

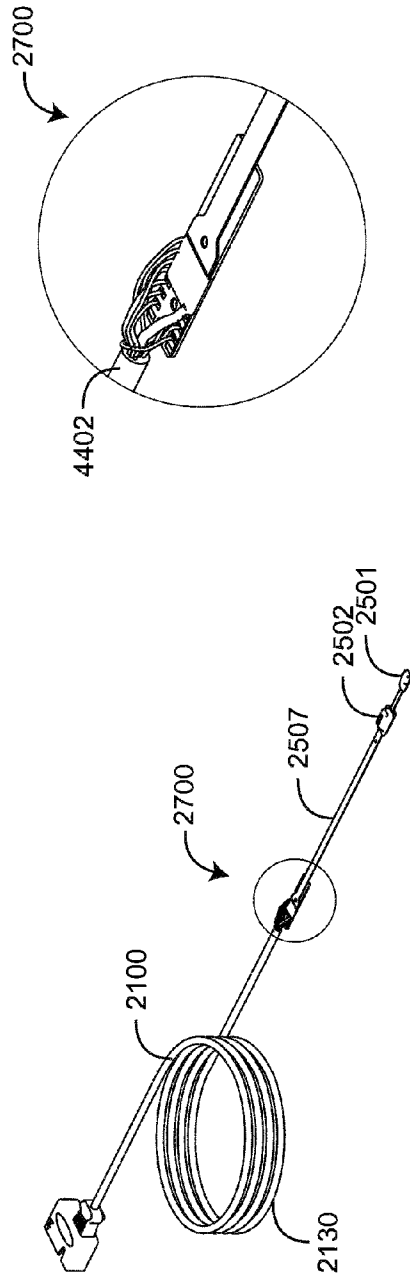


FIG. 27A

FIG. 27B

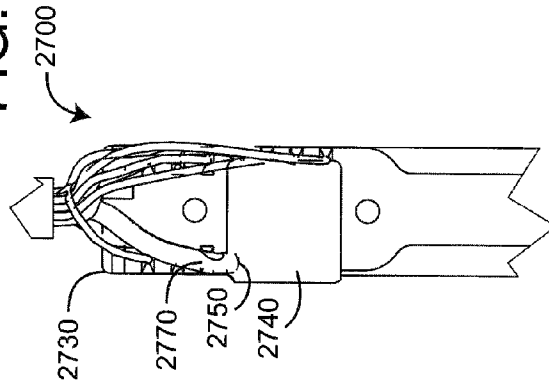


FIG. 27C

FIG. 27D

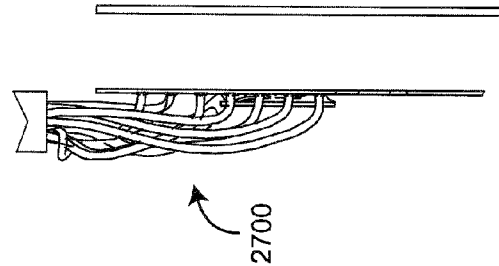
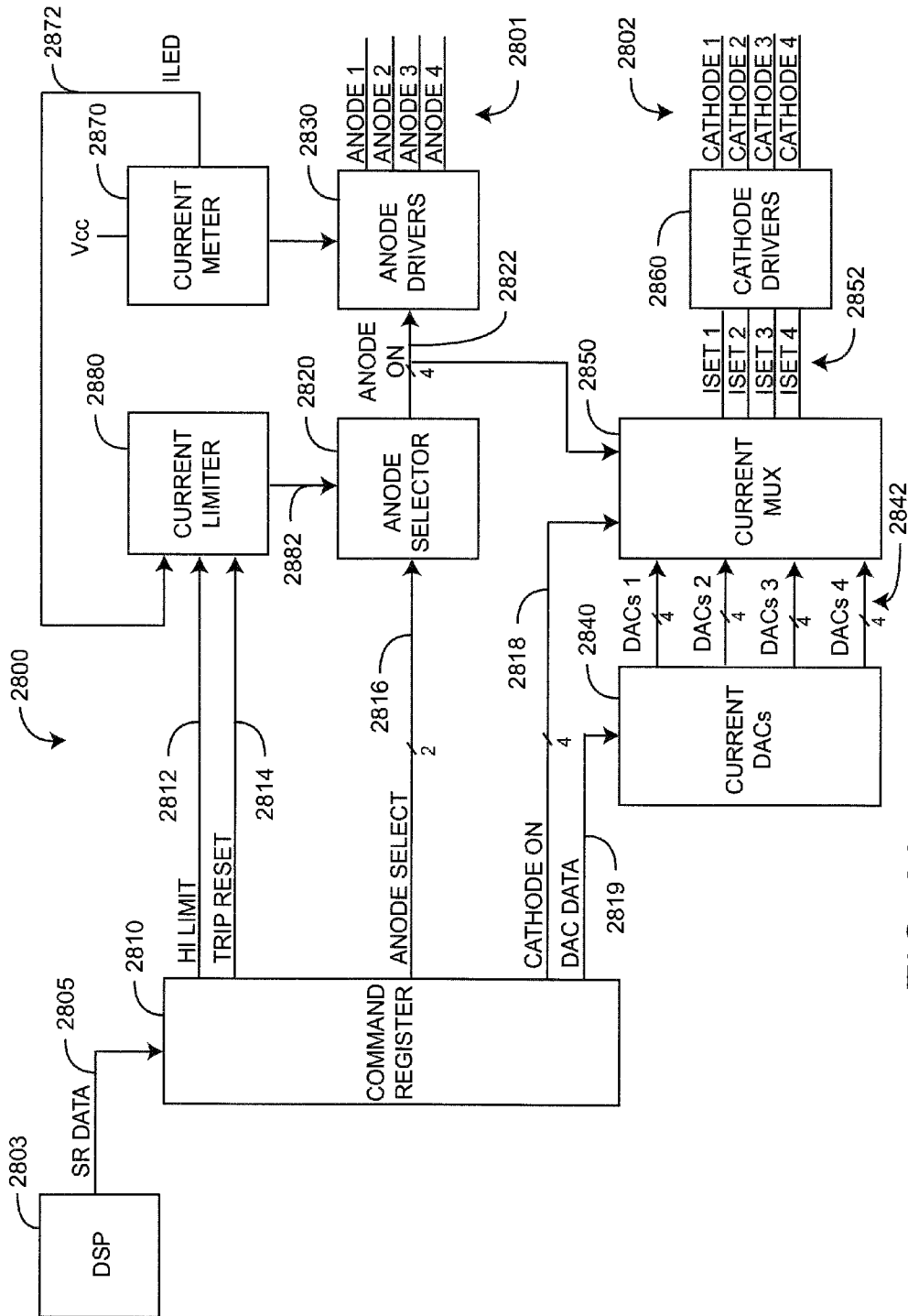


FIG. 27E



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**MULTIPLE WAVELENGTH OPTICAL
SENSOR****PRIORITY CLAIM TO RELATED PROVISIONAL
APPLICATIONS**

The present application claims priority benefit under 35 U.S.C. §119(e) to U.S. Provisional patent application Ser. No. 60/920,474, filed Mar. 27, 2007, titled Disposable Multiple Wavelength Optical Sensor, No. 60/923,630, filed Apr. 14, 2007, titled Disposable Multiple Wavelength Optical Sensor, and No. 61/033,007, filed Mar. 2, 2008, titled Multiple Wavelength Optical Sensor. All of the above-referenced applications are hereby incorporated by reference herein.

**INCORPORATION BY REFERENCE OF
COPENDING RELATED CASES**

The present disclosure is generally related to U.S. Provisional Application Ser. No. 60/998,659, filed Oct. 12, 2007, titled Ceramic Emitter Substrate; U.S. Provisional Application Ser. No. 60/979,658, filed Oct. 12, 2007, titled Ceramic Detectors; U.S. Provisional Application Ser. No. 60/979,674, filed Oct. 12, 2007, titled Connector Assembly; U.S. Design patent application Ser. No. 29/296,064, filed Oct. 12, 2007, titled Connector Assembly; U.S. Design patent application Ser. No. 29/296,067, filed Oct. 12, 2007, titled Connector Assembly; U.S. Provisional patent application Ser. No. 61/032,936, filed Feb. 29, 2008, titled Connector Assembly; and U.S. Design patent application Ser. No. 29/304,439, filed Feb. 29, 2008, titled Connector. All of the above-referenced applications are hereby incorporated by reference herein.

BACKGROUND OF THE INVENTION

Pulse oximetry systems for measuring constituents of circulating blood have gained rapid acceptance in a wide variety of medical applications including surgical wards, intensive care and neonatal units, general wards, home care, physical training, and virtually all types of monitoring scenarios. A pulse oximetry system generally includes an optical sensor applied to a patient, a monitor for processing sensor signals and displaying results and a patient cable electrically interconnecting the sensor and the monitor. A pulse oximetry sensor has light emitting diodes (LEDs), typically one emitting a red wavelength and one emitting an infrared (IR) wavelength, and a photodiode detector. The emitters and detector are attached to a patient tissue site, such as a finger. The patient cable transmits drive signals to these emitters from the monitor, and the emitters respond to the drive signals to transmit light into the tissue site. The detector generates a signal responsive to the emitted light after attenuation by pulsatile blood flow within the tissue site. The patient cable transmits the detector signal to the monitor, which processes the signal to provide a numerical readout of physiological parameters such as oxygen saturation (SpO₂) and pulse rate. Advanced physiological monitoring systems utilize multiple wavelength sensors and multiple parameter monitors to provide enhanced measurement capabilities including, for example, the measurement of carboxyhemoglobin (HbCO), methemoglobin (HbMet) and total hemoglobin (Hbt).

Pulse oximeters capable of reading through motion induced noise are disclosed in at least U.S. Pat. Nos. 6,770,028, 6,658,276, 6,650,917, 6,157,850, 6,002,952, 5,769,785, and 5,758,644; low noise pulse oximetry sensors are disclosed in at least U.S. Pat. Nos. 6,088,607 and 5,782,757; all

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of which are assigned to Masimo Corporation, Irvine, Calif. ("Masimo") and are incorporated by reference herein.

Physiological monitors and corresponding multiple wavelength optical sensors are described in at least U.S. patent application Ser. No. 11/367,013, filed Mar. 1, 2006 and titled Multiple Wavelength Sensor Emitters and U.S. patent application Ser. No. 11/366,208, filed Mar. 1, 2006 and titled Noninvasive Multi-Parameter Patient Monitor, both assigned to Masimo Laboratories, Irvine, Calif. (Masimo Labs) and both incorporated by reference herein.

Further, physiological monitoring systems that include low noise optical sensors and pulse oximetry monitors, such as any of LNOP® adhesive or reusable sensors, SofTouch™ sensors, Hi-Fi Trauma™ or Blue™ sensors; and any of Radical®, SatShare™, Rad-9™, Rad-5™, Rad-5v™ or PPO4™ Masimo SET® pulse oximeters, are all available from Masimo. Physiological monitoring systems including multiple wavelength sensors and corresponding noninvasive blood parameter monitors, such as Rainbow™ adhesive and reusable sensors and RAD-57™ and Radical-7™ monitors for measuring SpO₂, pulse rate, perfusion index, signal quality, HbCO and HbMet among other parameters are also available from Masimo.

SUMMARY OF THE INVENTION

There is a need to noninvasively measure multiple physiological parameters, other than, or in addition to, oxygen saturation and pulse rate. For example, hemoglobin parameters that are also significant are total hemoglobin (Hbt) and the percentage of carboxyhemoglobin and methemoglobin. Other blood parameters that may be amenable to noninvasive optical sensor measurement are fractional oxygen saturation, bilirubin and blood glucose, to name a few.

One aspect of a physiological sensor is an emitter that emits light having a plurality of wavelengths. A detector generates an output signal responsive to the emitted light after absorption by tissue. An attachment assembly removably attaches the emitter and the detector to tissue. A spacer provides a predetermined gap between the emitter and tissue when the emitter is attached to tissue. A light scattering medium is disposed in an optical path between the emitter and tissue. The spacer and the light scattering medium provide at least a substantially uniform illumination of tissue by the emitted light for each of the wavelengths. In various embodiments, the light scattering medium comprises glass beads mixed with an encapsulant disposed proximate the spacer. The light scattering medium comprises microspheres mixed with an epoxy disposed proximate the emitter. The emitter comprises an array of at least eight light emitting diodes emitting light generally centered around eight unique wavelengths. The emitter comprises an array of at least thirteen light emitting diodes emitting light generally centered around at least twelve unique wavelengths. The detector comprises at least one Si photodiode and at least one InGaAs photodiode connected in parallel. The detector comprises two Si photodiodes and four InGaAs photodiodes all connected in parallel. The light emitting diodes emit light within a first range of about 620-905 nm and within a second range of about 1040-1270 nm.

Another aspect of a physiological sensor comprising an emitter configured to radiate light having a plurality of wavelengths into a tissue site. The emitter comprises a plurality of LEDs disposed within an emitter ceramic substrate. A detector is configured to receive the light after absorption by pulsatile blood flow within the tissue site. The detector generates a sensor signal capable of being processed by a patient moni-

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tor so as to derive total hemoglobin (Hbt). The detector comprises a plurality of photodiodes disposed within a detector ceramic substrate. A first set of the photodiodes is responsive to a first set of the wavelengths and a second set of the photodiodes is responsive to a second set of the wavelengths. In various embodiments a diffuser scatters the radiated light so that a tissue site is uniformly illuminated across all of the wavelengths. A first encapsulate containing glass beads is mounted in a spacer proximate the emitter ceramic substrate. A second encapsulate mixed with microspheres is disposed on the LEDs within the emitter ceramic substrate. The photodiodes comprise at least one Si photodiode and at least one InGaAs photodiode connected in parallel. The LEDs radiate light generally centered around at least twelve unique wavelengths. The LEDs are mounted in an array of at least thirteen LEDs connected within an electrical grid. The twelve unique wavelengths comprise eight wavelengths within a first range of about 620-905 nm. and four wavelengths within a second range of about 1040-1270 nm.

A further aspect of a physiological sensor comprises a light source that radiates light having a plurality of wavelengths, a diffuser that scatters the radiated light so that a tissue site is uniformly illuminated across all of the wavelengths, and at least one detector that generates a sensor signal responsive to the radiated light after tissue attenuation. In an embodiment, the light source comprises a ceramic substrate having conductors arranged as an electrical grid and a plurality of LEDs mounted within the ceramic substrate in an array. In other embodiments, the diffuser comprises a first encapsulant having microspheres disposed over the LEDs; and a second encapsulant having glass beads disposed proximate the ceramic substrate. A spacer is disposed proximate the ceramic substrate so as to form a gap between the LEDs and the tissue site. A connector connects to a patient cable so as to communicate the sensor signal to a monitor. A flexible coupling has an optical end proximate the light source and the detector and a connector end proximate the connector. The flexible coupling has conductors that communicate the sensor signal from the optical end to the connector end.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of a physiological measurement system;

FIG. 2 is a general block diagram of a physiological measurement system;

FIG. 3 are block diagrams of a multiple wavelength optical sensor and a monitor;

FIG. 4 is a general block diagram of an emitter assembly;

FIG. 5 is a general block diagram of a detector assembly;

FIG. 6 is a general block diagram of an emitter array;

FIG. 7 is a block diagram of an emitter component;

FIG. 8 is a block diagram of a circuit substrate;

FIGS. 9A-B are perspective views of multiple wavelength optical sensor embodiments;

FIG. 10 is a perspective view of a patient cable and corresponding sensor connector;

FIGS. 11A-B are exploded perspective views of multiple wavelength optical sensor embodiments;

FIGS. 12A-C are exploded perspective views of an optical assembly;

FIG. 13 is an exploded perspective view of a contact assembly;

FIGS. 14A-D are exploded perspective views, and perspective and side views, respectively, of a connector assembly;

FIGS. 15A-B are perspective views of emitters;

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FIGS. 16A-H are top, cross-sectional, side and bottom views, respectively, of emitter embodiments;

FIGS. 17A-B are perspective views of a detector components;

FIGS. 18A-H are top, cross-sectional, side and bottom views, respectively, of detector components;

FIGS. 19A-B are perspective and top views, respectively, of a detector;

FIGS. 20A-B are top views of detector component embodiments;

FIGS. 21A-B are perspective views of multiple wavelength optical sensor embodiments;

FIG. 22 is a perspective view of an emitter assembly;

FIGS. 23A-D are bottom, side, top and perspective views of an emitter assembly;

FIGS. 24A-D are views of an encapsulated emitter assembly;

FIG. 25 is an exploded, perspective view of an optical assembly;

FIGS. 26A-I are assembly views for an optical assembly;

FIGS. 27A-E are views of a cable connection assembly; and

FIG. 28 is a general block diagram of an emitter driver.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

FIG. 1 illustrates a physiological measurement system 100 having a monitor 110 and a multiple wavelength optical sensor 120 with enhanced measurement capabilities as compared with conventional pulse oximetry. In particular, the multiple wavelength optical sensor 120 allows the measurement of various blood constituents and related parameters in addition to oxygen saturation and pulse rate. Alternatively, the multiple wavelength optical sensor 120 allows the measurement of oxygen saturation and pulse rate with increased accuracy or robustness as compared with conventional pulse oximetry.

In one embodiment, the optical sensor 120 is configured to plug into a monitor sensor port 112 via a patient cable 130. Monitor keys 114 provide control over operating modes and alarms, to name a few. A display 116 provides readouts of measured parameters, such as oxygen saturation, pulse rate, HbCO, HbMet and Hbt to name a few. Other blood parameters that may be measured to provide important clinical information are fractional oxygen saturation, bilirubin and blood glucose, to name a few.

In this application, reference is made to many blood parameters. Some references that have common shorthand designations are referenced through such shorthand designations. For example, as used herein, HbCO designates carboxyhemoglobin, HbMet designates methemoglobin, and Hbt designates total hemoglobin. Other shorthand designations such as COHb, MetHb, and tHb are also common in the art for these same constituents. These constituents are generally reported in terms of a percentage, often referred to as saturation, relative concentration or fractional saturation. Total hemoglobin is generally reported as a concentration in g/dL. The use of the particular shorthand designators presented in this application does not restrict the term to any particular manner in which the designated constituent is reported.

FIG. 2 illustrates a block diagram a physiological measurement system 200. This measurement system includes a monitor 210 and an optical sensor 220 communicating via a patient cable 230. The monitor 210 has one or more processor boards 250 communicating with a host instrument 280. Generally, the processor board 250 communicates with the sensor 220 so as to control the emission of light into a tissue site 10. Also the

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processor board **250** receives and processes a corresponding sensor signal responsive to the emitted light after scattering and absorption by tissue site constituents. Accordingly, the processor board **250** derives physiological parameters relating to pulsatile blood flow within the tissue site and communicates values for those parameters to the host instrument **280**. Generally, the host instrument **280** provides user I/O and communications with external devices so as to define operating conditions and communicate those conditions to the processor board **250**. The host instrument **280** also transfers parameter values from the processor board for display and for triggering alarms.

In an embodiment, the optical sensor **220** includes an emitter array **222**, at least one detector **224**, a temperature sensor **226** and a memory **228**. The emitter array **222** irradiates a tissue site **10** with multiple wavelength light. One or more detectors **224** detect the light after attenuation by the tissue site **10**. The temperature sensor **226** is located so as to detect the bulk temperature of the emitters within the emitter array, so as to accurately determine emitter wavelengths, as described below. The memory **228** can include any of a wide variety of memory devices known to an artisan from the disclosure herein, including an EPROM, an EEPROM, a flash memory, a ROM, a non-volatile RAM and a two-terminal serial memory device, to name a few, and combinations of the same. The memory **228** can advantageously store a wide variety of sensor-related information, including sensor type, manufacturer information, sensor characteristics including wavelengths emitted, wavelength correction data, emitter drive requirements, demodulation data, calculation mode data, calibration data and sensor life data to name a few. The memory can also store software such as scripts and executable code, encryption information, monitor and algorithm upgrade instructions and enabled parameters.

Although described herein with respect to various disposable sensor embodiments, a sensor may be reusable, responsible (partially reusable/partially disposable), adhesive or non-adhesive, or a transmittance, reflectance or transreflectance sensor. Further, a sensor may be configured for a variety of tissue sites such as a finger, hand, foot, forehead or ear or for attachment to multiple tissue sites, including multiple-head sensors capable of simultaneous multi-site measurements.

As shown in FIG. 2, the processor board **250** includes a front end signal conditioner **252**, an analog-to-digital (A/D) converter **253**, a digital signal processor (DSP) **258**, a memory reader **256**, emitter drivers **254** and digital-to-analog (D/A) converters **255**. In general, the drivers **254** convert digital control signals into analog drive signals capable of activating the emitter array **222**. The front-end **252** and A/D converter **253** transform composite analog intensity signal(s) from light sensitive detector(s) **224** into digital data input to the DSP **258**. In an embodiment, the DSP **258** is adapted to communicate via a reader **256** with one or more information elements such as the memory **228**.

According to an embodiment, the DSP **258** comprises a processing device based on the Super Harvard ARChitecture ("SHARC"), such as those commercially available from Analog Devices. However, the DSP **258** can comprise a wide variety of data and/or signal processors capable of executing programs for determining physiological parameters from input data. According to an embodiment, the processor board **250** may comprise one or more microcontrollers (not shown) for board management, including, for example, communications of calculated parameter data and the like to the host instrument **280**.

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Also shown in FIG. 2, the host instrument **280** communicates with the processor board **250** to receive signals indicative of the physiological parameter information calculated by the DSP **258**. The host instrument **280** preferably includes one or more display devices, alarms, user I/O and communication ports **284**. The alarms may be audible or visual indicators or both. The user I/O may be, as examples, keypads, touch screens, pointing devices or voice recognition devices. The displays may be indicators, numerics or graphics for displaying one or more of a pulse rate, plethysmograph data, signal quality, perfusion index and blood constituents values, such as SpO₂, carboxyhemoglobin (HbCO), methemoglobin (HbMet) and total hemoglobin (Hbt), or the like. The host instrument **280** may also be capable of storing or displaying historical or trending data related to one or more of the measured values or combinations of the measured values. A patient monitor is disclosed in U.S. App. No. 11,367,033, filed on Mar. 1, 2006, titled Noninvasive Multi-Parameter Patient Monitor, which is assigned to Masimo and incorporated by reference herein.

FIG. 3 illustrates a physiological measurement system **300** having a monitor **310** and a multiple wavelength sensor **320**. The sensor **320** has an emitter assembly **340**, a detector assembly **350**, an interconnect assembly **360**, an attachment assembly **370** and a connector assembly **380**. The monitor **310** has a sensor controller **312** that communicates with the sensor **320** via a cable **330**. As but one example, the sensor controller **312** may include emitter drivers, detector signal conditioning circuitry, A/D and D/A connectors, and a DSP incorporated onto a processor board, such as described with respect to FIG. 2, above.

As shown in FIG. 3, the emitter assembly **340** responds to drive signals received from the sensor controller **312** so as to emit light having a plurality of wavelengths. The detector assembly **350** provides a sensor signal to the sensor controller **312** in response to the emitted light after absorption by a tissue site. The interconnect assembly **360** mechanically mounts the emitter assembly **340** and the detector assembly **350** and provides electrical communication between the cable **330** and these assemblies **340**, **350**. The attachment assembly **370** attaches the emitter assembly **340** and detector assembly **350** to a tissue site. The connector assembly **380** provides a mechanical and electrical interface to the connector at one end of the cable **330**. A tape assembly example of an attachment assembly is described with respect to FIGS. 11A-B, below. A contact assembly example of a connector assembly is described with respect to FIGS. 13-14, below.

FIG. 4 illustrates an emitter assembly **400** having a substrate **410**, an emitter array **420**, an equalization **430** and a diffusion **440**. The emitter array **420** has multiple light emitting sources, each activated by drive signals **422**. The light emitting sources are capable of generating light **442** having multiple wavelengths. The equalization **430** accounts for differences in emitter intensity and tissue absorption of the light across the multiple wavelengths so as to at least partially equalize wavelength-dependent variations in intensity at the detector. The substrate **410** provides a physical mount for the emitter array and emitter-related equalization and an electrical connection between the emitter array and an interconnect assembly, such as described above. Advantageously, the substrate **410** also maintains a uniform bulk temperature measurement so as to calculate the operating wavelengths for the light emitting sources. One example of an emitter array embodiment **420** is described with respect to FIG. 6, below. One example of equalization **430** is described with respect to

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encapsulants, below. Examples of substrates **410** are described with respect to ceramic and board substrates, below.

FIG. **5** illustrates a detector assembly **500** including a substrate **510**, detector(s) **520** and an EMI shield **530**. The substrate **510** acts as a mechanical support for, and provides electrical contacts to, the detector(s) **520**. In an embodiment, the substrate **510** acts as an electrical insulator allowing the detector(s) **520** to be electrically isolated from EMI shielding **530** applied to a detector component. In an embodiment, the substrate **510** is a ceramic material.

FIG. **6** illustrates an emitter array **600** having multiple light emitters (LE) **610** capable of emitting light having multiple wavelengths. Row drivers **670** and column drivers **690** are electrically connected to the light emitters **610** and activate one or more light emitters **610** by addressing at least one row **620** and at least one column **640** of an electrical grid. In one embodiment, the light emitters **610** each include a first contact **612** and a second contact **614**. The first contact **612** of a first subset **630** of light emitters is in communication with a first conductor **620** of the electrical grid. The second contact **614** of a second subset **650** of light emitters is in communication with a second conductor **640**.

FIG. **7** illustrates an example of an emitter assembly **700** having light emitting diodes **710**, a temperature sensor **720** and a substrate **730**. The substrate **730** provides a thermal mass so as to stabilize a bulk temperature for the LEDs **710**. A temperature sensor **720** is thermally coupled to the substrate **730** so as to output, say, a current responsive to the bulk temperature T_b . The LED wavelengths **712** are determinable as a function of the drive currents **740** and the temperature sensor output **722**. In an embodiment, the substrate **730** is a ceramic material or, alternatively, a circuit board material having multiple materialization layers for thermal mass.

In one embodiment, an operating wavelength λ_a of each LED **710** is determined according to EQ. 1:

$$\lambda_a = f(T_b, I_{drive}, \Sigma I_{drive}) \quad (1)$$

where T_b is the bulk temperature, I_{drive} is the drive current for a particular LED, as determined by a sensor controller, and ΣI_{drive} is the total drive current for all LEDs. In another embodiment, temperature sensors are configured to measure the temperature of each LED **710** and an operating wavelength λ_a of each light emitter is determined according to EQ. 2:

$$\lambda_a = f(T_a, I_{drive}, \Sigma I_{drive}) \quad (2)$$

where T_a is the temperature of a particular light emitter, I_{drive} is the drive current for that light emitter and ΣI_{drive} is the total drive current for all light emitters.

In yet another embodiment, an operating wavelength for each LED is determined by measuring the junction voltage for each LED **710**. In a further embodiment, the temperature of each LED **710** is controlled, such as by one or more Peltier cells coupled to each LED **710**, and an operating wavelength for each LED **710** is determined as a function of the resulting controlled temperature or temperatures. In other embodiments, the operating wavelength for each LED **710** is determined directly, for example by attaching a charge coupled device (CCD) to each light emitter or by attaching a fiberoptic to each light emitter and coupling the fiberoptics to a wavelength measuring device, to name a few.

FIG. **8** illustrates an interconnect assembly **800** having a circuit substrate **810**, an emitter mount **830**, a detector mount **820** and a connector mount **840**. The emitter mount **830** mounts and electrically connects to an emitter assembly **860** having multiple light emitters. The detector mount **820**

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mounts and electrically connects to a detector assembly **850** having a detector. The connector mount **840** attaches a connector **870** having conductors that mate with a patient cable connector **890**. A first plurality of conductors disposed on the circuit substrate **810** electrically interconnect the emitter mount **830** and the connector **870**. A second plurality of conductors disposed on the circuit substrate **810** electrically interconnect the detector mount **820** and the connector **870**.

FIGS. **9A-B** illustrate embodiments of a multiple wavelength optical sensor. In particular, illustrated are a disposable sensor **900** including an adult/pediatric sensor **901** configured for finger placement and an infant/neonate sensor **902** configured for toe, foot or hand placement. Each sensor **900** has a tape end **910** and an opposite connector end **920** electrically and mechanically interconnected via a flexible coupling **930**. The tape end **910** attaches an emitter and detector to a tissue site, as described below. The emitter illuminates the tissue site and the detector generates a sensor signal responsive to the light after tissue absorption, such as absorption by pulsatile arterial blood flow within the tissue site. The sensor signal is communicated via the flexible coupling **930** to the connector end **920**. The connector mates with a cable (not shown) that communicates the sensor signal to a monitor (not shown). The monitor calculates a variety of physiological parameters from the detector signal, such as pulse rate (PR), oxygen saturation (SpO_2), carboxyhemoglobin (HbCO), methemoglobin (Hb-Met) and total hemoglobin (Hbt), to name a few. A sensor configured for measurement of at least some of the above-mentioned physiological parameters is described in U.S. Provisional Application Ser. No. 60/920,474, filed Mar. 27, 2007, titled Disposable Multiple Wavelength Optical Sensor; and U.S. Provisional Application Ser. No. 60/923,630, filed Apr. 14, 2007, titled Disposable Multiple Wavelength Optical Sensor, both applications incorporated by reference herein.

FIG. **10** illustrates an optical sensor **900** connecting with a patient cable **1000**. In the illustrated embodiment, the sensor **900** connects to the patient cable **1000** via a 15-pin sensor connector **1010** that mates with a 15-socket patient cable connector **1020**. In various embodiments, the sensor connector **1010** may have all of the pins electrically active, and, in other embodiments, only a subset of the pins may be active and used to communicate sensor signals. For example, in one embodiment only 9 pins are active. In other embodiments, the sensor connector may be a standard SpO_2 sensor, having, for example, a 9-pin mini-D connector, which is well known in the art. A latch **1060** disposed on the sensor connector **1010** is configured to engage a catch **1030** disposed on the patient cable connector **1020** so as to releasably hold the sensor connector **1010** and patient cable connector **1020** together. The sensor connector **1010** and patient cable connector **1020** are connected by pressing them together until the latch **1060** clicks into the catch **1030** and separated by pulling them apart while pressing downward on the latch **1060**, thereby disengaging the latch **1060** from the catch **1030**. In one embodiment, the monitor connector **1050** is a 20-pin DB connector. An example of a sensor connector is described with respect to FIGS. **13-14**.

FIGS. **11A-B** illustrate sensor assemblies **1100**, including an "I" configuration **1101** for adult/pediatric sensors and an "L" configuration **1102** for infant/neonate sensors. A sensor assembly **1100** has a flexible coupling **1110** interconnecting optical components **1200** at an optical end and connector components **1300** at a connector end. The coupling **1110** includes a flex circuit **1112**, a top sleeve **1114** and a bottom sleeve **1116**. The top sleeve **1114** and bottom sleeve **1116** interlock to create a channel which encloses a flex circuit **1112**. In one embodiment, the sleeve **1114**, **1116** is comprised

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of silicone rubber. The flex circuit **1112** mounts the optical components **1200** and a contact assembly **1300** and provides electrical communications between the optical components **1200** and the connector components **1400**, including the contact assembly **1300**. In an embodiment, base-tape, center-tape, face-tape and release liner layers **1150** are attached to “two-up” untaped assemblies and then cut to shape so as to provide an attachment assembly at tape end **910** (FIGS. 9A-B) for tissue attachment, described above.

FIGS. 12A-C further illustrate optical components **1200** having emitter components **1220** and a detector **1250** mounted to a flex circuit **1210**. The emitter components **1220** include a cover **1222**, a light block **1224**, an emitter **1280**, a spacer **1226** and an encapsulant **1228**. Advantageously, the spacer **1226** and encapsulant **1228** provide a relatively uniform illumination of a tissue site across all emitted wavelengths. In particular, the spacer **1226** provides a gap between the emitter **1280** and a tissue site, allowing emitted light from, say, individual LEDs of the emitter **1280** to spread as the multiple wavelength light propagates to a tissue site. Further, the encapsulant **1228** can be configured to diffuse or scatter emitted light as the light propagates to a tissue site. In an embodiment, the spacer **1226** gap is 70 mm. In an embodiment, the encapsulant **1228** contains 0.1 mm glass beads, 25% by weight, in a clear silicon RTV. In an embodiment, the emitter has an epoxy fill over LEDs incorporated within the emitter that contain microspheres so as to diffuse or scatter LED transmitted light, as described below. In an embodiment, an attenuation epoxy is dispersed over selected emitter LEDs so as to equalize intensities of the various LEDs, also as described, below. LED intensity equalization is disclosed in U.S. patent application Ser. No. 11/366,995, filed Mar. 1, 2006, titled Multiple Wavelength Sensor Equalization, incorporated by reference herein. In an embodiment, the encapsulant or LED fill or both provide notch filter characteristics according to emitted wavelengths so as to substantially attenuate secondary emissions from one or more LEDs.

As shown in FIGS. 12B-C, the flex circuit **1210** terminates a first solder plate **1212** which is generally rectangular and connected to and is slightly wider than a first connection arm **1211**. In an “I” configuration **1201**, the first connection arm **1211** bends along its length in order to accommodate a second solder plate **1214**. In an “L” configuration **1202**, the first connection arm **1211** has a generally right-angle bend away from the second solder plate **1214**. The second solder plate **1214** terminates a second connection arm **1213**. In an embodiment, the first solder plate **1212** has three solder pads arranged in a triangular fashion for connecting to corresponding detector solder pads. The second solder plate **1214** has ten smaller solder pads arranged in rows for connecting to corresponding emitter solder pads. It is well known in the art to include conductors and conductor paths on one or more sides of the flex circuit **1210**. In various embodiments, the shape of the flex circuit **1210** may vary. For instance, in some embodiments, the flex circuit **1210** may vary in length and the bends, if any, may vary in characteristics.

FIG. 13 illustrates a contact assembly **1300** having a connector plug **1310** that mates with a flex circuit connector plate **1218**. The connector plate **1218** forms one end of the flex circuit **1210** in communication with solder plates **1212**, **1214** (FIGS. 12B-C) at an opposite end of the flex circuit **1210**. The connector plug **1310** has a generally rectangular base **1311** and pins **1315**. The base **1311** has a front **1312**, a back **1313** and pin apertures **1314** extending through the base **1311**. The pin apertures **1314** are arranged in two rows, and the pins **1315** extend through the apertures **1314** so that a relatively long plug portion of the pins **1315** extends from base front

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1312 and a relatively short solder portion of the pins **1315** extends from the base back **1313**. The solder portion of the pins **1315** extend through and are fixedly soldered within corresponding connector plate apertures **1320**. In one embodiment, the base **1311** is comprised of a PC-ABS blend and the pins **1315** are comprised of a brass, bronze or copper base with gold plating.

As shown in FIG. 13, the connector plate **1218** has plug apertures **1320**, a flap **1330**, memory pads **1340**, resistor pads **1350** and a peg aperture **1360**. The flap **430** folds over a detector pin portion of the plug apertures **1320** so as to provide shielding for detector pins, which communicate a sensor signal from the detector **1250** (FIGS. 12A-C) to a patient monitor. The peg aperture **1360** is configured to accommodate a shell peg **1422** (FIG. 14A), securing the flex circuit **1210** to the sleeve **1114**, **1116** (FIGS. 11A-B) and connector shell **1410**, **1420** (FIGS. 14A-B). At least one memory **1370** is soldered to the memory pads **1340**. In one embodiment, the memory **1370** is a 20K EEPROM advantageously providing various sensor identification, diagnostic and control functions. In an embodiment, two 20K EEPROMs are utilized.

FIGS. 14A-D illustrate a connector **1400** having a top shell **1410**, a bottom shell **1420**, a clip **1430** and a contact assembly **1300**. The connector front has a passageway **1401** that accommodates a mating patient cable connector. A positioning tab **1424** abuts the flex circuit connector plate **1218** (FIG. 13). Apertures **1412** secure the clip **1430** by accommodating clip pegs **1432**. The connector back has a passageway **1402** that accommodates the flexible coupling **1110**. A shell peg **1422** engages a sleeve aperture **1450**, which secures the flex circuit **1112** and sleeve **1110** to the connector shell **1410**, **1420**. In one embodiment, the connector shell **1410**, **1420** is a PC-ABS blend.

The clip **1430** has a sloping latch **1438** located underneath the clip front **1434** and a lever **1030** (FIG. 10) extending from the clip back. The latch **1438** snaps into a corresponding catch of a mating patient cable connector. Advantageously, the lever **1436** is rigidly connected to the clip front **1434** and corresponding latch **1438** so that pressing downward with a finger or thumb on the lever **1436** raises the latch so as to disengage it from the corresponding catch **1030** (FIG. 10). As such, the clip **1430** advantageously releasably holds the connector **1400** to a mating patient cable connector **1020** (FIG. 10) so as to reduce accidental disconnects and provide for relatively straightforward and efficient connection and release. In certain embodiments, the clip **1430** releases without depressing the lever **1436** when a threshold of tension is placed on the connection. This avoids equipment damage and injuries if a sensor is accidentally jerked by a patient. In one embodiment, the clip **1430** is comprised of a PC-ABS blend.

FIGS. 15A-B illustrate emitters **1500**, including an eight-LED emitter **1501** particularly advantageously for SpO₂, HbCO and HbMet measurements and a thirteen-LED emitter **1502** particularly advantageously for total hemoglobin (Hbt) measurements in addition to SpO₂, HbCO and HbMet. Each emitter **1500** has a ceramic substrate **1510**, light-emitting diodes (LEDs) **1520** and a thermistor **1530**. The ceramic substrate **1510** has a body **1512** defining a cavity **1514**. The cavity **1514** contains bonding pads that mount an array of LEDs **1520**. The ceramic substrate **1510** also has multiple layers of traces, feed-thrus and solder pads so as to interconnect the LEDs **1520** in an electrical grid. The solder pads allow a monitor to electrically activate the LEDs **1520** via the flex circuit **1112** (FIGS. 11A-B), the connector **1010** (FIG. 10) and an attached patient cable **1000** (FIG. 10). The cavity **1514** also contains a thermistor **1530**, the resistance of which can be measured in order to determine the bulk temperature of

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the LEDs **1520**. The thermal characteristics of ceramic stabilize and normalize the bulk temperature of the substrate **1510** so that the thermistor measurement of bulk temperature allows an accurate determination of LED temperature and, hence, LED wavelengths.

As shown in FIGS. **15A-B**, an LED array **1520** is connected within an electrical grid of n rows and m columns totaling $n \times m$ LED drive lines where n and m are integers greater than one. The electrical grid advantageously minimizes the number of drive lines required to activate the LEDs **1520** while preserving flexibility to selectively activate individual LEDs **1520** in any sequence and multiple LEDs **1520** simultaneously. The electrical grid also facilitates setting LED currents so as to control intensity at each LED wavelength, determining operating wavelengths and monitoring total grid current so as to limit power dissipation. The LED array **1520** is physically configured in rows, which facilitates clustering LEDs according to wavelength so as to minimize pathlength variations and which facilitates equalization of LED intensities. In an embodiment the LED array **1520** comprises up to sixteen LEDs configured in an electrical grid of four rows and four columns. Each of four row drive lines provide a common anode connection to four LEDs, and each of four column drive lines provide a common cathode connection to four LEDs. Thus, sixteen LEDs are advantageously driven with only eight wires, including four anode drive lines and four cathode drive lines. In an embodiment, an LED array is partially populated with eight LEDs having nominal wavelengths as shown in TABLE 1. In an embodiment, the LED array is partially populated with thirteen LEDs having nominal wavelengths as shown in TABLE 2. Advantageously, LED array and the corresponding LED wavelengths are adapted to measure total hemoglobin (Hbt) in addition to SpO_2 , pulse rate, HbCO and HbMet, among other physiological parameters. In an embodiment, LEDs **D1-D5** are encapsulated with an attenuating epoxy **1660** (FIGS. **16B, F**) so as to equalize LED intensities. In an embodiment, a clear fill epoxy **1670** (FIGS. **16B, F**) mixed with 1-20 μm microspheres is dispersed and cured over the LEDs. An LED array and corresponding drivers for an electrical grid are disclosed in U.S. patent application Ser. No. 11/367,013, filed Mar. 1, 2006, titled Multiple Wavelength Sensor Emitters, incorporated by reference herein.

TABLE 1

Nominal LED Wavelengths (in nm)			
LED	λ	Row	Col
D1	630	1	1
D2	620	1	2
D3		1	3
D4		1	4
D5	700	2	1
D6	720	2	2
D7	660	2	3
D8	805	2	4
D9	905	3	1
D10		3	2
D11		3	3
D12		3	4
D13	645	4	1
D14		4	2
D15		4	3
D16		4	4

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TABLE 2

Nominal LED Wavelengths (in nm)			
LED	λ	Row	Col
D1	700	1	1
D2	660	1	2
D3	730	1	3
D4	805	1	4
D5	905	2	1
D6		2	2
D7		2	3
D8		2	4
D9	630	3	1
D10	620	3	2
D11	1170	3	3
D12	1240	3	4
D13	645	4	1
D14	1270	4	2
D15	1040	4	3
D16	1270	4	4

FIGS. **16A-H** further illustrate emitters **1500** having bonding pads **1610**, mounting pads **1620**, solder pads **1630**, bonding wires **1640**, an optical filter **1660** and an encapsulant **1670**. The mounting pads **1620** mount and electrically connect a first side (anode or cathode) of the array of LEDs **1520** (FIGS. **15A-B**) into an electrical grid. The bonding pads **1610** electrically connect a second side (cathode or anode) of the LEDs **1520** (FIGS. **15A-B**) into the electrical grid, via bonding wires **1640**. The thermistor **1530** is also attached to a pair of mounting pads **1620**. Plated "feed-thru" holes electrically connect the mounting pads **1620** and the bonding pads **1610** on the ceramic substrate top side (FIGS. **16A, E**) with solder pads **1630** on the bottom side (FIGS. **16D, H**).

FIGS. **17A-B** illustrate detectors **1700** including a detector **1701** utilizing a single Si photodiode **1720** particularly advantageous for SpO_2 , HbCO and HbMet measurements and a detector **1702** utilizing multiple photodiodes **1720** particularly advantageous for total hemoglobin (Hbt) measurements in addition to SpO_2 , HbCO and HbMet. Each detector **1700** has a ceramic substrate **1710** and one or more photodiodes **1720**. The ceramic substrate **1710** has a body **1712** defining a cavity **1714**. The cavity **1714** contains bonding pads that mount the photodiode(s) **1720** and electrically connect the photodiode(s) **1720**, if more than one, in parallel. The solder pads (not visible) output detector current to a monitor via the flex circuit **1112** (FIGS. **11A-B**), the connector **1010** (FIG. **10**) and an attached patient cable **1000** (FIG. **10**). In an embodiment, a single Si photodiode **1720** is utilized. In an embodiment, multiple photodiodes advantageously utilize parallel connected combinations of one or more Si photodiodes and one or more InGaAs photodiodes. The Si photodiodes are generally responsive to red and shorter near-IR wavelengths. The InGaAs photodiodes are generally responsive to longer near-IR wavelengths. Thus, the parallel combination of Si and InGaAs photodiodes extends the bandwidth of the detector component **1700** over the entire range of nominal LED emitter wavelengths, described above, so as to allow a corresponding monitor to non-invasively measure a patient's total hemoglobin (Hbt) among other blood parameters.

FIGS. **18A-H** further illustrate a detector component **1700** having a ceramic substrate **1710**, solder pads **1810**, a mounting pad **1820**, bonding pads **1830**, wire bonds **1840**, Si photodiodes **1860** and InGaAs photodiodes **1870**. The photodiodes **1860, 1870** are mounted on a mounting pad **1820** electrically connected to a first solder pad **1810**. The photodiodes **1860, 1870** are wire bonded **1840** to a bonding pad

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1830 electrically connected to a second solder pad 1810. The solder pads 1810 include DET-, DET+ and GND pads that mount the detector component 1700/detector 1900 to a flex circuit 1210, as described with respect to FIGS. 12A-C, above. A clear epoxy 1880 fills the remainder of the detector cavity 1714 (FIGS. 17A-B).

FIGS. 19A-B illustrate a detector 1900 having a detector component 1700 and a shield 1910. The shield 1910 has a conductive surface 1920 defining windows 1930. The windows 1930 can be any shape appropriate to the passage of light and the blocking of electromagnetic noise. In an embodiment, the windows 1930 are large rectangles with minimal interconnect so as to allow for a substantial passage of emitted light to the photodiodes 1720. In an embodiment, the shield 1910 is soldered to the ceramic substrate 1710 on at least the four corners, electrically and mechanically coupling the shield 1910 to the ceramic substrate 1710 and allowing the shield to form one side of a Faraday cage. Mechanical coupling can be, for example, gluing, welding, soldering, screwing, snap fitting, or other suitable fastening. Electrical coupling can be, for example, soldering, wire bonding, die bonding, or other suitable forms of electrical connection. In an embodiment, the ceramic substrate 1710 is printed with shielding material to complete the Faraday cage. Additional shielding material can be attached to or plated on the ceramic substrate 1710.

FIGS. 20A-B illustrate other photodiode array configurations 2001, 2002. In an embodiment 2001, one or two relatively large surface area InGaAs photodiodes 2020 are mounted between two relatively large surface area Si photodiodes 2010. In an embodiment 2002, four relatively medium surface area photodiodes 2030, 2040 are arrayed so as to intersperse Si photodiodes 2030 and InGaAs photodiodes 2040. In other embodiments, various photodiodes of relatively small, medium and large surface areas and in various mixes of Si and InGaAs technologies are arranged in various topologies within the detector substrate cavity so as to advantageously measure total hemoglobin among other parameters. Other embodiments incorporate other photodiode technologies capable of measuring red and infrared wavelengths in addition to, or in lieu of, Si and InGaAs technologies.

FIGS. 21A-B illustrate additional embodiments of a multiple wavelength optical sensor 2100. In particular, disposable sensors include an adult/pediatric sensor 2101 and an infant/pediatric sensor 2102. Each sensor 2100 has a tape end 2110 and an opposite connector end 2120 electrically and mechanically interconnected via a cable 2130. The tape end 2110 attaches an emitter and detector to a tissue site. An emitter, described below, emits/transmits light into the tissue site and a detector, also described below, generates a sensor signal responsive to the emitted light after tissue absorption. The sensor signal is communicated via the cable 2130 to the connector 2120. The connector 2120 mates with a patient cable (not shown) that communicates the sensor signal to a monitor (not shown). The relative spacing between the emitter and detector are selected to obtain a desired alignment of the emitter and detector when the sensor is attached to the body tissue of a patient.

FIG. 22 illustrates an emitter 2200 embodiment having a board substrate 2210, an LED array 2220 and one or more encapsulants 2230. The LED array 2220 emits optical radiation having multiple wavelengths of predetermined nominal values, advantageously allowing multiple parameter measurements. In particular, the LED array 2220 has multiple light emitting diodes (LEDs) that are physically arranged and electrically connected in an electrical grid to facilitate drive control, equalization, and minimization of optical pathlength

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differences at particular wavelengths. The LEDs are each activated by addressing at least one row and at least one column of the electrical grid, as described above. At least a portion of the encapsulants 2230 are advantageously configured to provide intensity equalization across a specific LED subset. In an embodiment, the LEDs emit light having wavelengths generally centered around the values shown in TABLE 3.

TABLE 3

Nominal LED Wavelengths			
LED	λ	Row	Col
D1	630	1	1
D2	620	1	2
D3	610	1	3
D4		1	4
D5	700	2	1
D6	730	2	2
D7	660	2	3
D8	805	2	4
D9		3	1
D10		3	2
D11		3	3
D12	905	3	4
D13		4	1
D14		4	2
D15		4	3
D16		4	4

FIGS. 23A-D illustrate a component-populated board substrate 2300 having a board substrate 2200, a LED array 2220, a thermistor 2310, bonding pads 2320, component pads 2330 and solder pads 2340. The LED array 2220 is soldered to the component pads 2330, which are electrically connected to the solder pads 2340. Accordingly, the solder pads 2340 provide an electrical connection via a flex circuit, described below, between the LED array 2220 and a sensor drive (FIG. 28) located in a monitor (not shown). The thermistor 2310 provides a bulk temperature measurement of the LED array 2220 so as to better determine LED operating wavelengths. Either the N or P side of each LED die is electrically connected to the component pads 2330. The opposite P or N side of each LED die is electrically connected to the wire-bond pads 2320.

FIGS. 24A-D illustrate an encapsulated board substrate 2400 having board substrate 2200, a first encapsulant 2410 and a second encapsulant 2420. The first encapsulant is colored so as to provide an optical filter to equalize the intensities of a specific LED subset. This equalization accounts for differences in LED intensity across the multiple wavelengths so as to at least reduce wavelength-dependent variations in detected intensity. In a particular embodiment, the first encapsulant 2410 encapsulates the shorter wavelength LEDs.

FIG. 25 illustrates a flex circuit assembly 2500 including a flex circuit 2507 having an optics end 2508 and a cable end 2509. FIGS. 26A-I describe a detector circuit assembly 2501 and an emitter circuit assembly 2502 at the optics end 2508. FIG. 27 describes a cable assembly at the cable end 2509. The emitter circuit assembly 2502 has an emitter 2510, a spacer 2520, an encapsulant 2530, a light barrier 2540 and an emitter cover 2550. The detector circuit assembly 2501 has a detector 2560, an EMI shield 2570 and a detector cover 2580. Solder 2505 attaches the emitter 2510 to flex circuit pads. Solder 2555 also attaches the detector 2560 to flex circuit pads. Advantageously, the spacer 2520 and encapsulant 2530 provide a relatively uniform illumination of patient tissue across all emitted wavelengths. In particular, the spacer 2520 provides a gap between the emitter LEDs and patient tissue,

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allowing the emitted light from each LED to spread as it propagates to a tissue site. In an embodiment, the gap is 70 mm. In an embodiment, the encapsulant is configured to diffuse or scatter emitter light from each LED as it propagates to a tissue site. In an embodiment, the encapsulant contains 0.1 mm glass beads, 25% by weight, in a clear silicon RTV. In an embodiment, the encapsulant contains filtering media that provides pass-band characteristics for the emitted wavelengths of the emitter assembly or notch filter characteristics away from the emitted wavelengths so as to substantially attenuate secondary emissions of the LEDs.

FIGS. 26A-I illustrate the detector circuit assembly **2501** and the emitter circuit assembly **2502**. FIGS. 26A-E illustrates the detector assembly **2501** with an unfolded and folded EMI shield **2570**. FIGS. 26F-I illustrate folding of a light barrier **2540** around the emitter **2510**.

FIGS. 27A-E illustrate a cable assembly **2700**. The sensor cable **2100** is mounted to a cable connector **2730** extending from the cable end **2509** of the flex circuit **2507**. Detector wires **2770** are shielded at the flex circuit junction by a fold-over conductive ink flap **2740**, which is connected to a cable inner shield **2750**.

FIG. 28 illustrates a sensor controller **2800** located in a monitor **100** (not shown) and configured to provide anode drive signals **2801** and cathode drive signals **2802** to an LED array. The DSP (digital signal processor) **2803**, which performs signal processing functions for the monitor, also provides commands **2842** to the sensor controller **2800**. These commands determine drive signal **2801**, **2802** levels and timing. The sensor controller **2800** has a command register **2810**, an anode selector **2820**, anode drivers **2830**, current DACs (digital-to-analog converters) **2840**, a current multiplexer **2850**, cathode drivers **2860**, a current meter **2870** and a current limiter **2880**. The command register **2810** provides control signals responsive to the DSP commands **2842**. In one embodiment, the command register **2810** is a shift register that loads serial command data **2805** from the DSP **2803** and synchronously sets output bits that select or enable various functions within the sensor controller **2800**, as described below.

As shown in FIG. 28, the anode selector **2820** is responsive to anode select **2816** inputs from the command register **2810** that determine which LED array row is active. Accordingly, the anode selector **2820** sets one of the anode on **2822** outputs to the anode drivers **2830**, which pulls up to Vcc one of the anode outputs **2801** to the LED array.

Also shown in FIG. 28, the current DACs **2840** are responsive to command register data **2819** that determines the currents through each LED array column. In one embodiment, there are four, 12-bit DACs associated with each emitter array column, sixteen DACs in total. That is, there are four DAC outputs **2842** associated with each emitter array column corresponding to the currents associated with each row along that column. In a particular embodiment, all sixteen DACs **2840** are organized as a single shift register, and the command register **2810** serially clocks DAC data **2819** into the DACs **2840**. A current multiplexer **2850** is responsive to cathode on **2818** inputs from the command register **2810** and anode on **2822** inputs from the anode selector **2820** so as to convert the appropriate DAC outputs **2842** to current set **2852** inputs to the cathode drivers **2860**. The cathode drivers **2860** are responsive to the current set **2852** inputs to pull down to ground one to four of the cathode outputs **2802** to the LED array.

The current meter **2870** outputs a current measure **2872** that indicates the total LED current driving the LED array. The current limiter **2880** is responsive to the current measure

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2872 and limits specified by the command register **2810** so as to prevent excessive power dissipation by the LED array. The current limiter **2880** provides an enable **2882** output to the anode selector **2820**. A Hi Limit **2812** input specifies the higher of two preset current limits. The current limiter **2880** latches the enable **2882** output in an off condition when the current limit is exceeded, disabling the anode selector **2820**. A trip reset **2814** input resets the enable **2882** output to re-enable the anode selector **2820**.

A multiple wavelength sensor has been disclosed in detail in connection with various embodiments. These embodiments are disclosed by way of examples only and are not to limit the scope of the claims that follow. Although a multiple wavelength sensor has been disclosed with respect to various disposable sensor embodiments, other embodiments incorporate other tissue site attachment technologies including reusable and resposable sensors configured to attach to various tissue sites including fingers, hands, feet, toes, ears to name a few. Further, although a multiple wavelength sensor has been disclosed with respect to light transmission with respect to emitters, tissue site and detectors, other embodiments incorporate reflectance and transreflectance configurations. A reusable sensor is disclosed in U.S. patent application Ser. No. 11/366,833, filed Mar. 1, 2006, titled Multiple Wavelength Sensor Attachment, incorporated by reference herein. One of ordinary skill in art will appreciate many variations and modifications.

What is claimed is:

1. A physiological sensor comprising:

an emitter that emits light having a plurality of wavelengths;

a detector that generates an output signal responsive to the emitted light after absorption by tissue, the detector comprising a plurality of Si photodiodes and at least one InGaAs photodiode connected in parallel;

an attachment assembly that removably attaches the emitter and the detector to tissue;

a spacer that provides a predetermined gap between the emitter and tissue when the emitter is attached to tissue; and

a light scattering medium disposed in an optical path between the emitter and tissue;

the spacer and the light scattering medium providing at least a substantially uniform illumination of tissue by the emitted light for at least one of the wavelengths, wherein the at least one InGaAs photodiode is mounted interspersed with the plurality of Si photodiodes.

2. The physiological sensor according to claim 1 wherein the light scattering medium comprises glass beads mixed with an encapsulant disposed proximate the spacer.

3. The physiological sensor according to claim 2 wherein the light scattering medium further comprises microspheres mixed with an epoxy disposed proximate the emitter.

4. The physiological sensor according to claim 3 wherein the emitter comprises an array of at least eight light emitting diodes emitting light generally centered around eight unique wavelengths.

5. The physiological sensor according to claim 4 wherein the emitter comprises an array of at least thirteen light emitting diodes emitting light generally centered around at least twelve unique wavelengths.

6. The physiological sensor according to claim 1 wherein the detector comprises two Si photodiodes and four InGaAs photodiodes all connected in parallel.

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7. The physiological sensor according to claim 4 wherein the light emitting diodes emit light within a first range of about 620-905 nm. and within a second range of about 1040-1270 nm.

8. The physiological sensor according to claim 1 wherein the detector includes at least two InGaAs photodiodes mounted between two Si photodiodes.

9. A physiological sensor comprising:

an emitter configured to radiate light having a plurality of wavelengths into a tissue site;

the emitter comprises a plurality of LEDs disposed within an emitter ceramic substrate;

a detector configured to receive the light after absorption by pulsatile blood flow within the tissue site;

the detector generates a sensor signal capable of being processed by a patient monitor so as to derive total hemoglobin (Hbt);

the detector comprises a plurality of photodiodes disposed within a detector ceramic substrate; and

a first set of the photodiodes is responsive to a first set of the wavelengths and a second set of the photodiodes is responsive to a second set of the wavelengths,

wherein the plurality of photodiodes comprises a plurality of Si photodiodes and at least one InGaAs photodiode connected in parallel, and wherein the at least one InGaAs photodiode is mounted interspersed with the plurality of Si photodiodes.

10. The physiological sensor according to claim 9 further comprising a diffuser that scatters the radiated light so that a tissue site is uniformly illuminated across all of the wavelengths.

11. The physiological sensor according to claim 10 wherein the diffuser comprises at least one of:

a first encapsulate containing glass beads mounted in a spacer proximate the emitter ceramic substrate; and

a second encapsulate mixed with microspheres disposed on at least one of the plurality of LEDs within the emitter ceramic substrate.

12. The physiological sensor according to claim 9 wherein the LEDs radiate light generally centered around at least twelve unique wavelengths.

13. The physiological sensor according to claim 12 wherein the LEDs are mounted in an array of at least thirteen LEDs connected within an electrical grid.

14. The physiological sensor according to claim 13 wherein the twelve unique wavelengths comprise eight wave-

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lengths within a first range of about 620-905 nm. and four wavelengths within a second range of about 1040-1270 nm.

15. The physiological sensor according to claim 9 wherein the detector includes at least two InGaAs photodiodes mounted between two Si photodiodes.

16. A physiological sensor comprising:

a light source that radiates light having a plurality of wavelengths;

a diffuser that scatters the radiated light so that a tissue site is uniformly illuminated across all of the wavelengths; and

at least one detector that generates a sensor signal responsive to the radiated light after tissue attenuation, the at least one detector comprising a plurality of Si photodiodes and at least one InGaAs photodiode connected in parallel, wherein the at least one InGaAs photodiode is mounted interspersed with the plurality of Si photodiodes.

17. The physiological sensor according to claim 16 wherein the at least one detector includes at least two InGaAs photodiodes mounted between two Si photodiodes.

18. The physiological sensor according to claim 16 wherein the light source comprises:

a ceramic substrate having conductors arranged as an electrical grid; and

a plurality of LEDs mounted within the ceramic substrate in an array.

19. The physiological sensor according to claim 18 wherein the comprises:

a first encapsulant having microspheres disposed over the LEDs; and

a second encapsulant having glass beads disposed proximate the ceramic substrate.

20. The physiological sensor according to claim 19 further comprising a spacer disposed proximate the ceramic substrate so as to form a gap between the LEDs and the tissue site.

21. The physiological sensor according to claim 20 further comprising:

a connector that connects to a patient cable so as to communicate the sensor signal to a monitor;

a flexible coupling having an optical end proximate the light source and the detector and a connector end proximate the connector; and

the flexible coupling having conductors that communicate the sensor signal from the optical end to the connector end.

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